



Innovative Medicines Initiative

IMI Financial Guidelines

VERSION 2 of 20 June 2013

These guidelines aim at **assisting all IMI consortia** during the **negotiation phase** and **all individual participants** during the **implementation of IMI** projects to clarify the provisions of the IMI model grant agreement (to which references are made throughout this document). The guidelines should therefore be read in connection with it.

The current **IMI model grant agreement** (last modifications adopted by the IMI JU Governing Board on 13 March 2013) can be found under:

http://www.imi.europa.eu/content/documents#grant_agreement

The guidelines are provided for information purposes only and the contents are **not intended to replace consultation of any applicable legal sources**, especially the provisions of the IMI grant agreement.

These guidelines are structured as follows:

- **Part 1** sets up the **general principles** applicable to all participants (beneficiaries, EFPIA companies and their affiliates, and any other participants);
- **Part 2** focuses on specific provisions only applicable to the **beneficiaries**;
- **Part 3** focuses on specific provisions only applicable to **EFPIA companies** (including their affiliates).

The present version is the first update of the document since its publication on 17 January 2012. It introduces the necessary clarifications and well established interpretation resulting from the experience, and reflects recent modifications in the IMI model grant agreement. The main changes concern:

- EFPIA provision to IMI project of samples and compounds as in-kind contribution (see part 1 section 2.6.9 *Costs specific to the pharmaceutical sector*)
- Exchange rate for EFPIA companies with accounts in currencies other than EUR and having a certified methodology for the calculation of the in-kind contribution (see part 1 section 6.4)
- Competitive calls (article II.43, see part 2 section 2.3)
- EFPIA Non-EU in-kind contribution (see Annex II of this Guide)
- Clinical sites participating in clinical trials under IMI projects (see Annex III of this Guide)

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EXECUTIVE SUMMARY

Introduction

The Innovative Medicines Initiative Joint Undertaking (IMI JU) is Europe's largest public-private partnership aiming to improve the drug development process by supporting a more efficient discovery and development of better and safer medicines for patients.

IMI is a Joint Undertaking between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

IMI budget of up to €2 billion is being invested until 2017. The European Union's contribution of maximum €1 billion will be entirely awarded to the public sector, academia, patient organisations and small and medium-sized enterprises (SMEs). The pharmaceutical industry will match this amount with €1 billion in R&D resources to fund its own contribution and the running costs of the IMI JU.

The IMI JU research activities support the implementation of research priorities set out in its Research Agenda mainly by awarding grants following [Calls for proposals](#).

The research consortia participating in IMI projects consist of:

- large biopharmaceutical companies that are members of EFPIA,
- and a variety of other partners, such as:
- small- and medium-sized enterprises,
 - patients' organisations,
 - universities and other research organisations,
 - hospitals,
 - regulatory agencies,
 - any other industrial partners.

Basic principles

The **legal entities eligible for IMI funding** are the following:

- Academia
- SMEs (according to the EU definition)
- Patient organisations
- Non-profit research organisations
- Intergovernmental organisations

These entities are defined as beneficiaries

The **legal entities not eligible for IMI funding** are the following:

- EFPIA companies (including their affiliates)
- Any type of organisation not included in the above list of IMI eligible legal entities, (e.g. private companies not falling within the EU definition of SMEs). Despite

not receiving IMI funding, where necessary, this kind of organizations may anyway participate in IMI projects under the Grant Agreement special clause No.11 (*Participants which are neither a beneficiary nor an EFPIA company*)

IMI may co-finance:

- Direct eligible costs (personnel, consumables, equipment, etc.)
- Indirect eligible costs = overheads calculated according a flat-rate of 20% of direct eligible costs (excluding subcontracting and third party costs incurred outside premises of a beneficiary), or actual indirect costs

The table below provides **summary of direct eligible costs**: For further details, please refer to Part 1-section 2.5 Identification of direct costs

	Indicative types of direct eligible costs
a) Personnel costs	Personnel on payroll of an entity who works on its premises for the IMI project. This may be either actual costs or average personnel costs (such as FTE). Average personnel costs may include other direct costs and also indirect costs, if this is consistent with the management principles and accounting practices of the entity.
b) Equipment	If the durable equipment is needed for the purpose of the IMI project, the relevant part of the depreciation according to the time used for the project can be charged. Calculation of depreciation should follow the company's own internal standard.
c) Consumables	<ul style="list-style-type: none"> ▪ Costs of general consumables incurred during the duration of the project should be calculated if not part of indirect costs or included in FTE rate, following each company's internal standard. Besides general consumables, within this category can also be considered animal costs: rat and mice, housing, transgenic mice animals and associated husbandry costs; transportation of animals/samples to partners in the consortium; ▪ samples, , compounds, DNA chip, ...
d) Subcontracting	<p>Examples:</p> <ul style="list-style-type: none"> ▪ studies subcontracted to a clinical research organisation (CRO); ▪ regulatory costs (EMA fees for scientific advice). ▪ Certificate on the financial statements

e) Other direct costs	<p>Example:</p> <ul style="list-style-type: none"> ▪ costs for personnel allocated for activities related to management of the project; ▪ travel and subsistence, ▪ rental costs for off-site meeting rooms, ▪ catering, etc.
	.

Funding rates are the following (only for **beneficiaries**):

- Research activities: a maximum of 75% of total eligible costs
- Other activities, including management and training activities: a maximum of 100% of total eligible costs

Structure of IMI grant agreement

The IMI grant agreement is structured as follows:

- Core grant agreement: Articles 1 to 11, including list of the applicable special clause(s) in Article 7
- Annex I: Description of Work
- Annex II: Article II.1 to II.43 (General Conditions)
- Annex III: Form to be signed by project participants for acceding to the IMI grant agreement (also called Form A)
- Annex IV: Form to be signed by new participants for acceding to the IMI grant agreement during the implementation of the project (also called Form B)
- Annex V: Templates for financial statements (also called Form C)
- Annex VI: Terms of reference for the certificate on the financial statements (also called Form D)

The list of special clauses can be found here:

http://www.imi.europa.eu/sites/default/files/uploads/documents/Rev_Grant_Agreement_2011/2_WP_2013_GA_Annex%20VII_Special%20Clauses_2013%2003%2013.pdf



Innovative Medicines Initiative

PART 1: GENERAL PRINCIPLES APPLYING TO ALL PARTICIPANTS

SECTION 1: ORGANISATION OF THE CONSORTIUM AND RESPECTIVE ROLES

1.1. Role of the coordinator (Article II.2.3)

The **coordinator** is the project leader and represents the consortium for any communication between the IMI JU and any participant of the project.

The coordinator:

- a) shall 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 the grant agreement and the decisions taken by the consortium;
- b) shall review the reports to verify consistency with the project tasks before transmitting them to the IMI JU;
- c) shall monitor the compliance by participants with their contractual obligations under the IMI grant agreement;

The coordinator is an EFPIA company, unless otherwise agreed within the consortium.

1.2. Role of the managing entity (Article II.2.3)

The **managing entity** of the IMI JU funding is a beneficiary and receives on behalf of the beneficiaries the IMI JU financial contribution to the project.

The managing entity 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 beneficiaries without unjustified delay.

1.3. Can the tasks of the coordinator and the managing entity be performed by other participants/third parties? (Article II.2.3)

The tasks attributed by article II.2.3 to the coordinator and the managing entity **cannot be subcontracted or outsourced to:**

- other participants; or
- a third party, except when the introduction of Special Clause 9 in the IMI grant agreement allows for the managing entity to delegate some of the tasks to a third party created by, controlled by or affiliated to the Managing Entity.

1.4. Can part of the management tasks be performed by other participants/third parties?

Some management tasks, such as participation to project management meetings, collection of the certificates on financial statements, may be performed by other participants, including the managing entity or a beneficiary. They will be reimbursed at 100% provided they comply with the other eligibility criteria as stipulated in Article II.13.

1.5. Can there be a scientific coordinator different from the scientific representative of the coordinator?

Tasks related to the coordination of the project that are not listed in Article II.2 of the IMI grant agreement (e.g. scientific coordination of the project) could be carried out by another participant, including by the managing entity.

The participant in charge of the task of scientific coordination, may be internally (i.e. within the Consortium) identified as a "scientific coordinator". However, in the relationship with the IMI JU, the "scientific coordinator" will not be considered as the project coordinator.

The tasks of scientific coordination performed by any participant can be reimbursed, if the said beneficiary complies with the criteria for eligibility established in Article II.13, but only as "research and technological development activities" (i.e. 75% reimbursement rate). By their nature (scientific work) they cannot be reimbursed as "management costs" (i.e. reimbursement up to 100%).

SECTION 2: FINANCIAL PROVISIONS

2.1. Estimated budget and maximum IMI JU contribution (Article 5)

The estimated budget and the maximum IMI JU financial contribution are based on an estimation of eligible costs prepared by the participants and negotiated with the IMI JU.

Estimation of eligible costs of the project must be shown in detail in the estimated breakdown of budget included in the Description of Work (Annex I).

Costs incurred by the participants in the course of the project, must satisfy the eligibility criteria laid down by the IMI grant agreement (Article II.13). It must be stressed that subject to these criteria, it is always the IMI JU which takes the final decision on the nature and amount of the costs to be considered eligible, either when analysing proposals for the establishment of the estimated budget to be annexed to the IMI grant agreement or when examining financial statements for the purposes of determining the IMI JU financial contribution.

2.2. Financial content of Annex I of the grant agreement (Description of Work): budget transfers among participants

In the Description of Work (Annex I) a copy of an estimated breakdown of budget must always be included (from SOFIA, table A3.2-*What it costs*).

As the estimated breakdown of budget included in the Description of Work (Annex I) is an estimate, the transfer of budget between activities and participants is allowed without the need for an amendment of the IMI grant agreement. However, a condition for this is that the work be carried out as foreseen in Annex I. The coordinator (together with the managing entity) should verify this on a case-by-case basis, but in practical terms, coordinators (and participants) are encouraged, where a transfer with a potential impact on the "Description of Work" arises (most cases), **to check this** (e.g. by e-mail) with the Scientific Officer in the IMI JU. This e-mail (or other written) communication would avoid disagreement on the interpretation of this condition later.

An amendment to Annex I of the IMI grant agreement will be necessary if the budget transfer arises from a significant change, i.e. change that affects the activities as foreseen in the Annex I, including the subcontracting of a task that was initially meant to be carried out by a participant.

Furthermore, if a transfer is made, the reimbursement rates of the new activities and beneficiaries concerned as described in Article II.15 will apply, as well as any other limits set in the IMI grant agreement (i.e. transfer between beneficiaries or activities with different funding rates).

2.3. Eligibility criteria

To be considered eligible, costs must be:

- *actual (Article II.13.1.a)*

Costs must be actually incurred (actual costs). That means that they must be real and not estimated, budgeted or imputed.

Where actual costs are not available at the time of establishment of the financial statements, the closest possible estimate can be declared as actual if this is in conformity with the accounting principles of the participant. This must be mentioned in the financial statement. Any necessary adjustments to these claims must be reported in the financial statement for the subsequent reporting period (see Section 5).

For the last period the costs should be submitted based on the information available at the moment of preparing the financial statement but the participant should always provide the closest possible estimate.

- *incurred by the participant (Article II.13.1.b)*

Supporting documents proving **occurrence**, the bookkeeping and the payment of the costs by the participants must be kept for all costs and for up to five years after the end of the project.

However, in some circumstances the IMI grant agreement accepts some third parties (i.e. any legal entity which does not sign the IMI grant agreement) whose costs may be eligible. Should a participant wish to recur to the assistance of a third party in an ongoing project, this has to be discussed with the Scientific Officer, and if approved and in conformity with the rules, the third party contribution and resources have to be detailed in Annex I. For further details, see Section 3.

- *incurred during the duration of the project (Article II.13.1.c)*

Only costs generated during the lifetime of the project can be eligible.

The starting date of the project determines the period of eligibility of the corresponding costs (Article 3 – Duration and start date of the project). The start date of the project cannot be prior to the submission of the Full Project Proposal, insofar the Full Project Proposal is deemed to have been concluded **before** the start of the project.

However, for participants working on accrual accountancy basis, the date when the costs are incurred is the date when they are entered into the books according to applicable national accounting rules. Therefore, for these participants' costs relating to e.g. travels, may be potentially eligible if the invoices documenting them were entered into the books after the start date of the project. The fact that costs must be incurred during the duration of the project does not necessarily mean that the cost has in fact to be paid during that period: e.g. salaries of staff for the last month of the project which are paid following the end of the project.

The IMI grant agreement foresees an explicit exception for 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. These costs may be incurred during the period of up to 60 days after the end of the project or the date of termination.

It may be that despite that the ownership of the good has actually been transferred **or the service provided** some costs have not yet been paid when the request for the final payment is sent. This situation is acceptable if it is certain that a debt exists (invoice or equivalent) for services or goods actually supplied during the lifetime of the project and the final cost is known; the IMI JU is entitled to check whether payment was actually made by asking for supporting documents to be produced when the payment has been made or during an *ex post* audit carried out later.

For the last period the costs should be submitted based on the information available at the moment of preparing the financial statement.

Can costs related to the drafting of the Full Project Proposal or Project Agreement be eligible?

Both the FPP and Project Agreement are prepared prior to the start of the project thus outside the cost eligibility window.. Consequently, costs related to preparing, drafting and submitting the Full Project Proposal are not eligible and can never be charged to the project. Likewise, costs associated with the Project Agreement, since it is deemed to have been concluded prior to the signature of the Grant Agreement and to the start of the project. However, costs related to amendments/modifications of the Project Agreement occurring during the project are eligible costs of the project.

Can depreciation costs for equipment used for the project but bought before the start of the project be eligible?

If the equipment has not yet been fully depreciated according to the usual accounting and management principles and practices of the participant, then the remaining depreciation (according to the amount of use, in percentage and time) can be eligible under the project.

Example:

Equipment bought in January 2010, with a depreciation period of 48 months according to the participant's accounting practices. If a project starts on 1st January 2012 (when 24 months of depreciation have already passed), and the equipment is used for this IMI project, the participant can declare the depreciation costs incurred under the project for the remaining 24 months (but only the portion of the equipment used on the project may be charged).

Can cost of consumables incurred before start date of the project be considered as eligible?

Based on scientific or technical justification with the prior agreement of IMI JU, some consumables used during the implementation of the project may be exceptionally considered. The rules are under definition along the following principles: this shall be valued and recorded according to the usual accounting and management principles and practices of the participant, and auditable.

Examples: Clinical samples or compounds pre-existing to the project, but which would be entirely used (destroyed) for the sole purpose of the specific IMI JU project.

- ***Determined according to the usual accounting and management principles and practices of the participant identifiable and verifiable (Article II.13.1.d)***

Costs must be determined according to the applicable accounting rules of the country where the participant is established and "*according to the usual accounting and management principles and practices of the participant*".

However, this principle is not absolute; it must be considered together with the other eligibility criteria, and therefore could not be invoked in order to deviate from other provisions of the IMI grant agreement.

Example: VAT could be considered as a cost by the accounting of a participant, but this cannot be used to claim it as an eligible cost with an IMI JU project, as VAT is not an eligible cost (article II.13.3.a of the IMI GA)

This also means that participants do not have the possibility to create specific accounting principles for IMI projects (e.g. a bonus payment for researchers only for the time spent on IMI projects).

Costs which cannot be justified are, as a matter of principle, to be considered not eligible. The IMI grant agreement states that "*the participant's internal accounting and auditing procedures must permit direct reconciliation of the costs and revenue declared in respect of the action with the corresponding accounting statements and supporting documents*".

However, for the participants who charge indirect costs using the flat rate of 20%, by definition these indirect costs do not need to be backed up by supporting evidence (see Article II.14.2.b)).

- ***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 (Article II.13.1.e)***

These costs must be essential for the performance of the project and would not be incurred if the project did not take place. The concept of correctly matching estimated costs and expected achievements is a fundamental criterion: the participant must be able to justify the resources used to attain the objectives set. The IMI JU grant must not be diverted to finance other projects or other activities.

The principles of economy, efficiency and effectiveness: refers to the standard of "good housekeeping" in spending public money effectively. Economy can be understood as minimising the costs of resources used for an activity (input), having regard to the appropriate quality and can be linked to efficiency, which is the relationship between the outputs and the resources used to produce them. Effectiveness is concerned with measuring the extent to which the objectives have been achieved and the relationship between the intended impact and the actual impact of an activity.

Costs must be reasonable and comply with the principles of sound financial management, with the objectives of the project and with the formal aspects of the

reporting of this expenditure, including the follow-up of the budget in terms of budget allocation and schedule of the cost.

- *recorded in the accounts of the participant and, in the case of any contribution from third parties, recorded in the accounts of the third parties (Article II.13.1.f)*
- *incurred for prospective research conducted in an EU Member State or associated country (Article II.13.1.g)*

The research activities for which reimbursement is claimed must be conducted in a Member State or in a country associated to the FP7.

However, on a predefined and exceptional basis, under certain conditions and subject to the IMI JU Governing Board decision, EFPIA in-kind contribution for research activities conducted outside a Member State or an associated country may be accepted project by project (please see section 3 paragraph 1.1, and Annex II- *Non-EU EFPIA in-kind contribution*).

- *have been indicated in the estimated overall budget annexed to the IMI grant agreement – Annex I (Article II.13.1.h)*

It is however possible, without a supplementary agreement, to authorise certain transfers of costs between eligible cost items in the estimated budget within the overall amount of eligible costs (Article 5.2).

2.4. Non-eligible costs (Article II.13.6)

Certain costs are specifically excluded from the eligible costs. The list of these costs mentioned in the IMI grant agreement must be regarded as a minimum reference list and must be fully complied with.

The following costs are not eligible:

- identifiable indirect taxes including value added tax

In general, the participant is entitled to charge to the project only the net value of the invoice, provided that all eligibility criteria are met. Identifiable VAT is not eligible. As mentioned above, indirect taxes will be allowed when not identifiable. This may be for example the case with foreign invoices where the price indicated is gross without identifying the tax. In any case, the participant should be able to justify this in the event of an audit.

The particular case of airport taxes

In general, airport taxes are not real taxes in the sense of tax law but a fee for a service delivered by a public or semi-public body in charge of a (public) service, such as airports (independent of the fact that some airports might have a private legal form). In this case the airport taxes imposed by these authorities may be considered a fee and therefore eligible because they are neither a duty nor an indirect tax. Usually the invoice makes reference to "service charge", "charge" etc. If the invoice, however, only mentions "airport taxes", the participant should use other means to prove that the so called "airport tax" is not a tax. As a conclusion, it can be said that when airport taxes are not identifiable, they are eligible, but when airport taxes are identifiable, the nature of the tax has to be examined according to the point above.

*Examples: Fuel surcharge, insurance surcharge, etc. are eligible costs;
Air passenger duty is not an eligible cost (see below)*

- duties: mean the amount assessed on an imported or (less often) exported item, nearly equivalent to taxes, embracing all taxation or charges levied on persons or things [or the tax imposed on the importation, exportation, or consumption of goods],
- interest owed,
- provisions for possible future losses or charges,
- exchange losses, cost related to return on capital,

Example: Cost related to return on capital e.g. if there are dividends paid as remuneration for the work in the project.

- costs declared or incurred, or reimbursed in respect of another Union project, (avoiding double funding)
- debt and debt service charges, excessive or reckless expenditure. Excessive should be understood as paying significantly more for products, services or personnel than the prevailing market rates, resulting in an avoidable financial loss to the project. Reckless means failing to exercise care in the selection of products, services or personnel resulting in an avoidable financial loss to the project.

2.5. Distinction between direct and indirect costs

Depending on the characteristics of the operation in question, it is possible that some costs can be considered either direct costs or indirect costs, but no cost can be taken into account twice as a direct cost and an indirect cost.

2.5.1. Direct costs

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.

Costs like personnel, durable equipment, travel and subsistence, subcontracting, consumables, etc. may be considered as direct eligible costs.

2.5.2. Indirect costs

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.

Indirect costs, also called overheads, are all the structural and support costs of an administrative, technical and logistical nature which are cross-cutting for the operation of the participant's various activities and cannot therefore be attributed in full to the project. The nature of an indirect cost is such that it is not possible, or at least not feasible, to measure directly how much of the cost is attributable to a single cost objective.

Example:

Overheads comprise costs connected with infrastructures and the general operation of the organisation such as hiring or depreciation of buildings and plant, water/gas/electricity, maintenance, insurance, supplies and petty office equipment, communication and connection costs, postage, etc. and costs connected with horizontal services such as administrative and financial management, human resources, training, legal advice, documentation, etc.

Indirect costs must be in accordance with normal accounting practices of the participant and should be extracted from or reconciled with the official accounts.

When the accounting system of the participant includes overhead costs which are not eligible under the IMI grant agreement, these costs must be removed when submitting financial reports.

2.6. Identification of direct costs (Article II.14.1)

2.6.1. Personnel costs

(a) Cost of personnel assigned to the project

- The personnel must be directly hired by the participant in accordance with its national legislation.
- The personnel must work under the sole technical supervision and responsibility of the participant.
- Any participant may include in its personnel costs "permanent employees", who have permanent working contracts with the participant or "temporary employees", who have temporary working contracts with the participant.
- Personnel costs should reflect the total remuneration: salaries plus social security charges (holiday pay, pension contribution, health insurance, etc.) and other statutory costs included in the remuneration.
- Personnel must be remunerated in accordance with the normal practices of the participant.

(a.1) Time recording: general principles

Only the hours worked on the project can be charged. Working time to be charged must be recorded **throughout the duration of the project by timesheets**, adequately supported by evidence of their reality and reliability. In the absence of timesheets, the participant must substantiate the cost claimed by reasonable means (alternative evidence) giving an equivalent level of assurance, to be assessed by the auditor. Employees have to record their time on a daily, weekly, or monthly basis using a paper or a computer-based system. The time records have to be authorised by the project manager or other superior.

Where it is the usual practice of the participant to consider certain types of personnel (such as administrative or support personnel) as indirect costs, the costs of this personnel cannot be charged as direct eligible costs, but only as indirect costs.

If a participant decides to use timesheets to record working hours then they should meet at least the basic requirements indicated below:

- full name of participant as indicated in the IMI grant agreement;
- full name of the employee directly contributing to IMI project;
- title of IMI project as indicated in the IMI grant agreement;
- project account number should be indicated;
- time period concerned (for instance on daily, weekly, monthly basis) according to the participant's normal practice;
- amount of hours claimed on the IMI project. All hours claimed must be able to be verified in a reliable manner;
- full name and a signature of a supervisor (person in charge of the project).
- the timesheets must be reconcilable with the absences for holidays, illness, travel, others.

Timesheets are NOT to be sent to the IMI JU. However they must be available at the participant's premises in case of audit, in order to evidence the time spent on the project.

In cases where personnel works on several projects during the same period the time recording system must enable complete reconciliation of total hours per person, listing all activities (EU projects, non EU projects, internally funded research, administration, absences etc.). It is important to remember that an effective time-recording system (a system/process which certifies the reality of the hours worked) is a requisite for the eligibility of the costs. This may be for example a printed version of an Excel sheet (duly signed) or a computer based time-keeping system. The objective is not to verify check in and check out times, but to evidence the time spent on a project.

A contract, as a document signed before the work is actually performed, would not be sufficient. It is worth mentioning that the above elements are the basic ones, thus there are no obstacles to running the timesheets in a more detailed way.

(a.2) Working hours and productive hours

A simple estimation of hours worked is not sufficient. Productive hours must be calculated according to the participant's normal practices.

The annual number of productive hours can be calculated in two ways:

- by using a standard number of productive hours used for all employees;
- by calculating an actual individual number of productive hours for each employee.

The first option, the use of the standard number of productive hours, is the most efficient one.

The second option, the use of actual productive hours per employee to compute the hourly personnel rate is the most precise. In general, the actual productive hours should be close to the standard productive hours. In addition, the time recording system of the participant should allow keeping track of this number of actual individual number of productive hours.

Productive hours include all working activities of the personnel of the participant; they include also activities such as:

- Sales and Marketing
- Preparation of proposals
- Administrative time
- "Unsold time"/ "non billable" hours

Productive hours per year should exclude annual leave, public holidays, training and sick leave. A figure of 210 working days- year could be considered representative in most cases

For example:

<i>Total days in a year</i>	<i>365</i>
<i>Weekends</i>	<i>-104</i>
<i>Annual holidays</i>	<i>-21</i>
<i>Statutory holidays</i>	<i>-15</i>
<i>Illness/Others</i>	<i>-15</i>

The above may vary depending on the personnel category, industry sector, unions, contracts and national legislation which should all be taken into account.

Moreover, some activities may be considered not to be part of the productive hours of personnel:

- Training (not project related¹)
- Internal meetings (not project related)

These activities together with the sickness days should not exceed 15 days a year (unless duly justified). The participant must substantiate these hours/days. In addition, this calculation should be consistent with the internal regulations and/or practice of the organisation (e.g. minimum number of training days specified in the organisation's HR policy) and/or the time recording system of the participant. (e.g. if internal meetings hours are deducted from the productive hours, the time recording system should keep track of the hours spent on meetings).

Productive hours have to be clearly justified and should match the underlying time records. If hours actually spent in productive tasks (as supported by time records) exceed the standard productive hours, the first shall be used for the calculation of the personnel costs,

The participant cannot claim more hours than the ones he used for the computation of the personnel hourly rates. Otherwise, it would charge more than its actual personnel costs. If the participant uses the standard productive hours, it cannot claim more hours than the standard productive hours, even if the actual time spent exceeds them.

If the participant uses the actual productive hours, it cannot claim more hours than the individual actual productive hours.

¹ Time spent on general training activities and/or general internal meetings can be deducted to arrive at the number of productive hours. Specific training activities and internal meetings which can be directly allocated to the project are part of the productive hours.

(a.3.) *Particular cases:*

- "Teleworking": may be accepted if there is a system that allows the identification of the productive hours worked for the project.
- Overtime: may be accepted provided that:
 - the overtime is actually paid,
 - the overtime is necessary to the project and in conformity with the participant's national legislation,
 - it is the policy of the participant to pay overtime. Only the hours worked on the project can be charged. The hourly rate applicable to these "overtime" hours has to be taken into account separately from the standard working hours and there must be a system that allows the identification of the productive hours worked for the project.
- Sick leave: cannot be included in the working time.
 - Parental leave of personnel assigned to the action: the amount of this allowance may be an eligible cost under certain conditions. Beneficiaries who deduct time for parental leave from the standard annual productive time are already compensated for such costs and therefore are not allowed to charge costs related to individual employees' parental leave to the specific RTD project. Beneficiaries who do not deduct time for parental leave from the standard annual productive time may charge such costs in proportion to the time dedicated to the project provided that they are mandatory under national law (e.g. statutory maternity pay), that the beneficiary has effectively incurred such costs, and that they are not compensated by the national or regional authorities. Only costs related to personnel who worked on the project before the parental leave may be eligible. Costs for the advertising to recruit a new person are not eligible but, if it is necessary for the project to replace the person, the costs of the new person will be eligible under the normal requirements.
- Bank charges: The general eligibility of bank charges depends on their nature. For example, debt service charges are not eligible (see Article II.13.6.g) but charges relating to transfers may constitute eligible costs relating to the management activity (provided that all eligibility criteria stipulated in the grant agreement are met). In principle these costs should be covered by the indirect costs. Where it is the usual practice of the beneficiary to consider these costs as indirect costs, they cannot be charged as direct eligible costs, but only as indirect costs. Therefore, if the beneficiary receives a flat rate for indirect costs, and bank charges are considered to be indirect costs under the usual accounting and management principles and practices of the beneficiary, then they cannot be charged as direct costs.
- Benefits in kind (company car, vouchers, etc.): may be accepted only if they are justified and in conformity with the usual practices of the participant. Like all costs, they should fulfil the conditions of Article II.13.
- Recruitment costs: In general, these costs are not eligible as direct personnel costs since the participant is required to have the human resources necessary for the action at the start of the project. If a participant needs to recruit additional personnel during the course of the project the relevant costs could

be considered as part of the normal indirect costs of the organisation if they fulfil the conditions of article II.13 and if it is the usual practice of the participant to pay for those costs.

- Redundancy payments are in principle not considered as eligible costs. However, if the obligation to pay redundancy provisions arises from a statutory obligation under the applicable national labour law, the payments might be considered as eligible costs of the project.
- PhD costs: eligible if they fulfil the conditions of Article II.13.1.
- For public bodies, the costs of public officials paid directly from central government or local government budgets may also be considered as eligible costs if the other provisions of Article II.13 are fulfilled. For more explanations please see Part 1 - Section 3.3 relating to the case of personnel (resources) made available by third parties to a participant.
- Bonus payments: As a general rule, payment of additional payments and bonuses that are not an employer's obligation arising from the national regulation relating to labour law or even from the employment contract and that are within its discretion may not be considered as part of normal remuneration, even though identified as a payment on the payroll, and their eligibility may be questioned (in particular with respect to the criterion of necessity for carrying out the project).

However, if such payments are part of the normal salary and benefit package of an employee they could be considered as part of the normal personnel costs. However, these costs have to be compliant with the eligibility criteria of Article II.13, in this case the most important of which will be the criterion of economy and coherence with the participant's usual accounting practices. The costs must be in conformity with the usual behaviour of the participant.

The following criteria should be applied to the “bonus payments” to be considered eligible. Failing to meet one of these criteria means, in principle, rejection of the "bonus payments":

- 1) The bonus scheme should be provided for in the internal regulations and/or practices of the organisation (calculation method, category of employees falling under this scheme, maximum amount, etc.);
- 2) The bonus scheme should apply to all projects (IMI, EU and other projects, national and international) of the same kind; i.e.; the bonus must be given to all international (EU and non EU) or to all national projects. Bonus schemes should be implemented in a consistent manner for the same type of activities/projects.;
- 3) The bonus payments should not result in a level of remuneration inconsistent with the current market conditions for a worker of the same category/grade/experience;
- 4) The bonus payments must be recorded in the accounts of the contractor as personnel costs and must be subject to taxes and social security charges applicable to salaries or specifically exempt from such taxes and/or charges.
- 5) These bonuses can only be paid as part of the employee's gross remuneration. The criteria (qualitative or financial targets, research activities carried out, contractor's profitability, etc) used to calculate the amount of the bonus can be accepted provided they are of general application within the beneficiary's organisation and are objective;

(b) The particular case of average personnel costs (Article II.13.2 for all participants and Article II.13.4 for EFPIA companies)

"Option 1" No methodology required

Only actual costs are in principle eligible for cost reimbursement. However, participants may opt to declare average personnel cost if the following cumulative criteria are fulfilled:

Criterion a: Usual cost accounting practice declared by the participant

The methodology applied should be the usual cost accounting practice of the participant. The terms *"...shall be the one declared by the participant"* means that the IMI JU will consider that by submitting and signing financial statements (Form C) calculated by means of a given methodology, the participant is declaring that such methodology is its usual costs accounting practice. Where necessary this usual cost accounting practice should be adjusted to fulfil all the eligibility criteria. For instance, this would be the case when the usual personnel cost calculation method includes ineligible items which would need to be removed (e.g. indirect taxes).

This criterion does not require the average personnel costs methodology to be equal for all types of employees, departments or cost centres. If, for instance, the usual cost accounting practice includes different calculation methods for permanent personnel and temporary personnel, this is acceptable.

Criterion b: Based on the statutory accounts

To guarantee that the average cost rates used in the methodology are based on actual costs, the calculation method should compute personnel cost rates resulting from the payroll figures registered in the statutory accounts of the entity.

Budgeted or estimated figures, except if authorised through the certified methodology on in-kind contribution as set forth in Part 3, are not costs actually incurred and, as such, cannot be accepted as eligible components of the personnel costs. Notwithstanding this, when the actual amount of some element of the personnel costs is not known at the time of the preparation of the financial statements (Form C), beneficiaries are entitled to use the last available financial data or the best possible estimation of the actual costs. In those cases, the costs claimed must be adjusted according to the actual costs incurred as registered in the beneficiary's accounts in the subsequent period or, at the latest, at the time of the submission of the final report of the project to IMI JU. The resulting adjustment to the costs already charged should be declared in an additional Form C indicating that it is an adjustment to a previous statement (by ticking out the yes option in the specific box).

Criterion c: Excluding ineligible costs and double funding

Cost declared to be ineligible by the IMI JU, in particular those enumerated in Article II.13.6, need to be removed from the personnel rates. If the usual accounting practice includes any element considered ineligible, the personnel rates would need to be adjusted by withdrawing such components from the pool of personnel cost.

The methodology should also prevent double funding of the same costs. As an example, certain methodologies include in the calculation of the personnel rates cost components which are part of the indirect costs in the beneficiaries' accounts. In such situations, if the beneficiary uses real indirect costs, the methodology should ensure that those items are removed from the pool of costs used to calculate the indirect cost charged to the IMI

projects. In the particular case of participants applying a flat-rate indirect cost method, the personnel cost cannot include any indirect cost element as these are covered by the flat-rate.

Criterion d: Productive time

As a general rule, the number of productive hours should be that applied as the usual practice of the participant. For instance, beneficiaries could use the actual productive hours of each researcher according to the time records or instead use a standard number of productive hours (generally annual productive hours). When the beneficiary applies a standard number of productive hours, this should be representative of its working standards. Background information used to determine the standard productive hours should be available and verifiable.

An illustrative example could be a case where a beneficiary deducts 7 working days a year as average illness absence of the employees when calculating the annual productive hours. The records substantiating this figure should be available in case of an audit.

"Option 2" *Certificates on the methodology for average personnel costs (CoMav)* *(Article II.4.5)*

Participants are no longer required to submit a Certificate on Average Personnel Costs (CoMAv) for approval as a prior condition for the eligibility of the costs. Nevertheless, the CoMAv remains as an option offering beneficiaries the possibility to obtain prior assurance on the compatibility of the methodology in place with FP7. All participants applying average personnel costs are entitled to submit a CoMav. Methodologies submitted for approval will be assessed against the criteria defined above. Procedures for the submission and treatment of the CoMav remain unchanged and can be consulted at the FP7 Guidance Notes for Beneficiaries and Auditors (http://cordis.europa.eu/fp7/find-doc_en.html).

"Option 3" *Certificates on the methodology for both personnel and indirect cost (COM)* *(Article II.4.5)*

Participants may decide to send such certificate for approval by the European Commission in the context of FP7. In case of approval, the requirements to provide a certificate on the financial statement for intermediate reporting periods shall be waived. See also section 6.1

(c) *The particular case of consultants*

Consultants are natural (physical) persons, working for one or more participants in an IMI project. They may be either self-employed or working for a third party.

There are three possible ways of classifying the costs of consultants (in any event costs will ONLY be eligible if they fulfil the conditions listed in Article II.13):

(c.1.) They can be considered as **personnel costs**; regardless of whether the intramuros consultants are self-employed or employed by a third party, if the following cumulative criteria are fulfilled:

- The participant has a contract to engage a physical person to work for it and some of that work involves tasks to be carried out under the project,
- The physical person must work under the instructions of the participant (i.e. the work is decided, designed and supervised by the participant),
- The physical person must work in the premises of the participant (except in the case of teleworking agreed between both parties),
- The result of the work belongs to the participant (Article II.26),
- The costs of employing the consultant are not significantly different from the personnel costs of employees of the same category working under labour law contract for the participant,
- The remuneration is based on working hours rather than on the delivering of specific outputs/products,
- Travel and subsistence costs related to such consultants' participation in project meetings or other travel relating to the project would have to be paid directly by the participant to be eligible.

(c.2.) Costs related to consultants can be considered as **subcontracting costs** if the participant has to enter into a subcontract to hire these consultants to perform part of the work to be carried out under the project and the conditions set out in the IMI grant agreement, in particular if the provisions of Article II.7 relating to subcontracting are fulfilled. See Section 3.4.2

The remuneration of the subcontractor is based on the delivering of specific outputs/products rather than on working hours (even if an estimate of the working hours necessary should be taken into account for the pricing).

(c.3.) The last possibility is that the consultant participates in the project as a beneficiary (either as a physical person or possibly as an SME, if it meets the definition).

(d) The particular case of physical persons, and SME owners (Article II.13.3)

For the eligibility of costs relating to personnel costs of owners of SME and other natural persons, there are two possibilities:

- either the owner receives a salary from the SME, in which case the salary is an eligible cost following normal rules,
- or the owner does not receive a salary for its work for the SME, and therefore no record of its personnel costs can be found in the accounts of the company.

SME owners and other natural persons who do not receive a salary shall charge as personal costs a flat rate based on the ones used in the FP7 'People' Work Programme of the year of publication of the Call to which the proposal was submitted(as referred to in Article II. 13.3, further information can be obtained on the FP7 Participant Portal at the following address: <http://ec.europa/research/participants/portal/page/people>)

It is important to bear in mind that the annual living allowance covers the total personnel costs; i.e. salaries plus social security charges (holiday pay, pension contribution, etc.). No other personnel costs (e.g. social insurance costs) related to the involvement of the SME owner/natural person in the project may be charged on top of the flat rate.

(e) The particular case of direct taxes and social charges

Social charges are normally considered eligible costs when specifically attributable to the project. Direct taxes and certain other charges related to personnel, however, are in general not considered to be eligible when deemed not to be incurred specifically for the implementation of a project, unless they are calculated on the basis of the individual salaries of the persons working on the project. However, participants tend to consider that all direct taxes and social charges linked to the remuneration of personnel are eligible, independently of the way they are calculated, as they are part of the full cost of employment related to research.

To address this issue, the IMI JU will recognise as being eligible direct taxes and social charges to the extent they fulfil all of the following criteria:

the charges are mandatory under the applicable legislation or sector agreements, or resulting from measures based on such legislation or agreements. These taxes and charges must relate to personnel costs allocated to the project. Taxes and charges calculated on the global payroll and inherent to the business of the entity are not deemed to fall within the scope of personnel costs and are therefore ineligible.

- they can be directly or indirectly² linked to the remuneration of personnel.

² This means that to satisfy this criterion the charges are not necessarily incurred for the specific individuals working on the projects funded under the contracts/grant agreements nor do they necessarily explicitly appear on the related payslip. Indeed, the related charges can be computed on the basis of specific accounting procedures, such as a pro rata charge on the overall employment costs of a legal entity and are fairly apportioned to the project. Taxes and charges for which the beneficiary is indebted for as a business entity, and having the nature of a business tax, are calculated on the "masse salariale" of the beneficiary, are not considered linked to the remuneration of personnel, in the sense of this paragraph.

- they are recorded according to the usual accounting principles of the participant concerned.
- they are effectively incurred during the duration of the project and have been paid or will be paid obligatorily at a later date and reflected in the accounts of the participant.

These principles will not be applied in cases of fraudulent claims for such costs.

A certain number of taxes and personnel charges and their eligibility have been examined under FP7 criteria. A non-exhaustive list can be found in the following document:

ftp://ftp.cordis.europa.eu/pub/fp7/docs/eligibility-taxes-charges_en.pdf

2.6.2. Travel and subsistence allowances for staff taking part in the project

- As a general rule, actual travel and related subsistence costs relating to the project may be considered as direct eligible costs, providing they comply with the participant's usual practices and are adequately recorded, like any other cost.

Example:

Participant A declares the flight costs of a project meeting for a member if its staff travelling in business class:

- *If the usual practice of the participant is to pay for business class tickets for staff of the same category, then the cost of the business class ticket will be eligible under the IMI grant agreement*
- *If the usual practice of the participant is to pay for economy class tickets for staff of the same category, then the cost of the business class ticket will not be eligible under the IMI grant agreement*
- There is no particular distinction regarding the eligibility of costs incurred for travelling outside or in Europe. Depending on the financial impact of the travel it might be convenient to discuss it with the IMI Scientific Officer.
- Travel costs must be needed for the work in the project, or for activities related to it (e.g. presentation of a paper explaining the results of the project in a conference). Travel costs related to a conference where no specific project-related work will be performed or presented by the participant would not be eligible. Travel costs should be limited to the necessity for the project; any extension of the travel for other professional or private reasons is not an eligible cost.
- Travel expenses of experts participating on punctual basis in the project (i.e. attendance to specific meetings) are not travel costs; however, they may be considered direct eligible costs, provided the participation of experts is duly foreseen in Annex I. These costs may be reimbursed to the experts by the participant or the participant may directly deal with the travel arrangements (and therefore be directly invoiced).
- If such costs are reimbursed on the basis of a lump sum/or per diem payment, it is the lump sum or per diem and not the actual costs that are considered to be eligible costs.

Where it is the usual practice of the participant to consider these costs as indirect costs, they cannot be charged as direct eligible costs, but only as indirect costs. On the other hand, if the contractor considers this category of costs on a direct basis, the same category (other travel and subsistence costs not attributed directly to projects) cannot be charged as indirect costs.

2.6.3. Equipment - Purchase cost of durable equipment

- Only equipment purchased for the purposes of carrying out the action can be charged as direct costs. To be considered as eligible, a cost must be determined according to the participant's usual accounting practice and each participant must apply its usual depreciation system for durable equipment. Depreciation is charged in each relevant periodic report. Depreciated costs of equipment can never exceed the purchase price of the equipment.

It is expected that the participant calculates depreciation on the durable equipment that it purchases. Depreciation cannot be spread over a period exceeding the useful life of the equipment. Participants should be aware that not doing so and charging the full price of an asset in one single year **might be considered an "excessive" cost** (as referred to in Art. II.13.6 (g)), and therefore be considered **ineligible**.

- Depreciation costs for equipment used for the project but bought before the start of the project are eligible under the conditions mentioned in Article II.13.1.
- Only the portion of the equipment used on the project may be charged. The amount of use (percentage used and time) must be auditable.

In some cases (e.g. Infrastructure) cost for equipment can include all those costs necessary for the asset to be in working condition for its intended use (site preparation, delivery and handling, installation, etc.).

Cash-based accounting: If the purchase cost of the equipment is recorded as an expense in the participant's accounting system in the period concerned (cash based accounting) and if this is its usual accounting practice and is in line with the national accounting regulation/law, it is acceptable to charge the entire purchase cost to the project in the period concerned under the following conditions:

- a) The cost must be economic and necessary.
- b) Only the portion of the equipment used on the project may be charged. The amount of use (percentage used and time) must be auditable. Thus if the equipment is used for other projects, part of the equipment cost will be charged to these projects.

Subcontracting vs. durable equipment/consumables: sometimes the purchase of equipment or consumables is associated with the provision of a service. Depending on the nature of the services provided, they may be considered subcontracts or part of the equipment purchase. If the service is part of the "package" of equipment purchase then it will be considered to be part of the equipment purchase. It may also depend on the consideration of these costs in the accounts of the participant.

- Financial leasing with the option to buy durable equipment shall be charged, in accordance with the participants' own accounting practices. However, to comply with the principle of sound financial management, the cost claimed for durable equipment which is leased with an option to buy cannot exceed the costs that

would have been incurred if the equipment had been purchased and depreciated under normal practices.

Operational leasing (renting): in this case, there is no possibility to buy the equipment. There is no depreciation involved (as the item is still the property of the leasing firm) but the costs are eligible if this follows the participant's normal practices and does not exceed the costs of purchase of the equipment

In both cases, if the participant does not use the equipment solely for the purposes of the project, only a proportionate part of the "working time" (i.e. that part used for the project) may be charged.

- Where it is the usual practice of the participant to consider durable equipment costs (or some of them) as indirect costs, those costs cannot be charged as direct costs, but as indirect costs.

2.6.4. Consumables and supplies

- Any consumables (e.g. data, samples, compounds, etc.) necessary for the implementation of the project may be considered as direct eligible costs under the conditions laid down in Article II.13.1.
- Where it is the usual practice of the participant to consider consumable costs (or some of them) as indirect costs, those costs cannot be charged as direct costs, but as indirect costs.

2.6.5. Subcontracting (Article II.7)

The costs of subcontracting may be direct eligible costs. See below section 3.4.1 Minor services (which do not need to be foreseen in Annex I) have to be declared also in Form C under subcontracting (not under other direct costs).

2.6.6. Costs of certificate on the financial statements (CFS) (Article II.4.4)

The costs incurred for the CFS are eligible under management activity; however a distinction has to be made between certificates issued by external auditors and certificates established by Competent Public Officers:

- Certificates issued by external auditors have to be treated as "subcontracting" costs under the management activity and therefore they will not be included in the overheads calculation;
- Certificates issued by Competent Public officers can be treated as "other direct costs" under the management activity.

The cost of the CFS is an eligible cost in the IMI grant agreement for which the certificate is submitted (Article II.15.3). Nevertheless, if the participant decides to submit a CFS voluntarily when it is not required by the IMU grant agreement (i.e. when the IMI JU financial contribution is less than EUR 375,000 for the intermediate periods), the costs of the CFS will not be eligible, since these costs are not considered as necessary.

See also below section 6.1.Certificate on the financial statements (Article II.4.4).

2.6.7. Conference fees

Conference fees are those paid to attend a conference for the necessity for the project. Necessity for the project can for example be established if the participant were to present a paper related to the research in the project. In any case, this participation should have been mentioned in Annex I; if it is not, it is recommended to contact the Scientific Officer of the IMI JU before participating in the conference so that the question can be examined.

2.6.8. Internally invoiced costs

Sometimes the use of certain equipment or facilities is shared between the different units **of the same legal entity**, and the costs of their use are charged through internal invoices. This type of costs may be eligible if their use for the project and the usage is properly recorded. In such cases, the costs claimed must represent a fair apportionment and be based on objective, measurable and auditable criteria.

Internally invoiced personnel costs for project specific activities may be eligible if the time worked on the project is substantiated by records covering all the workable time of the relevant personnel. The eligible hourly rate must be calculated based on the actual cost for salaries and social charges incurred by the participant.

Internal invoicing may apply also to items like animal maintenance, computer runs, laboratory tests and other similar services where it is difficult to substantiate the actual time and the actual cost of each individual involved in each individual operation, and where an average personnel cost per type of animal, type of computer run, type of test etc. has been calculated based on the actual costs incurred for the personnel involved. For these costs to be eligible the calculation of costs must be auditable.

The same logic applies to equipment, consumable or any other specific direct costs: where it is difficult to substantiate the actual cost of each individual test or use, an average cost may be calculated per type of test based on the actual cost of the equipment and consumables used and other specific direct costs such as maintenance of equipment provided. However, the calculation of costs must be auditable.

Internally invoiced **overheads** are normally not eligible as direct project costs.

2.6.9. Costs specific to the pharmaceutical sector

The following 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 - may be considered as direct eligible costs (this list is not exhaustive):

- Chemistry or biochemistry samples, compounds, DNA, cell lines, etc. generating value to the project.

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The need for using such consumables (compounds or samples) has to be stated together with the related value- in the Call text and/or in the Full Project Proposal (the FPP).

The full amount of samples and compounds supplied to the project should be entirely used up for and during the project. When not entirely used up, remaining sample or compound is returned to the originator or, upon agreement with IMI JU, used for other purposes than those described in the Description of Work (DoW). In such a case, any impact on the value of the in-kind contribution must be discussed with IMI JU. Furthermore, the originator must ensure that such consumables are not claimed as in-kind contribution for other IMI projects. The costs of such used consumables must be recorded and auditable according to the usual accounting and management principles (see also 2.3 Eligibility criteria).

Depending on the usual practice of the participant, such consumable costs may be declared either as direct or indirect costs.”

- Databases

The cost of building a database which were incurred before the start date of the project, or incurred outside a European member State or associated country, or which are not recorded in the accounts of the participants who is claiming them cannot be counted as eligible contribution. However, additional cost for extracting or reformatting the data may be eligible costs if recorded in the accounting.

- Innovative clinical trials to verify safety and efficacy

Clinical trials can be carried out internally by a participant or outsourced to a third party (subcontractor).

1) When carried out internally:

- the participant may either charge his actual costs of the trials; or
- where it is difficult to substantiate each of the actual costs involved for each individual test, the participant may opt to charge an average cost per patient or test or type of test, calculated with a methodology based on its actual costs and that is auditable.

2) The participant may also propose to outsource the performance of the clinical trials to a third party:

- either on a commercial basis by means of a subcontract, for which a price is

- agreed upon by the participant and the third party.
- or on a cost basis, on a non-commercial basis, that is where the third party charges only its costs to the participant who reimburses them fully and is in turn reimbursed by the IMI Joint Undertaking according to the applicable funding rate (please see Annex III - *Participation in IMI projects of clinical sites whose contribution to the project is limited to the recruitment and inclusion of patients into the trial*).

Participants are reminded that it is up to them to demonstrate that their choice of a third party secures the best value for money, for example by providing the various offers requested, or, if a long term-cooperation with that third party to carry out such tests pre-exists, to demonstrate its added value.

Participants that are public bodies are reminded that the selection of such a third party has to follow their internal rules and applicable legislation, in particular those related to public procurement, as a matter of eligibility. All studies must carefully consider the ethical and regulatory framework at the national, European and international level for the conduct of clinical trials. Even though the IMI Joint Undertaking may be co-funding a clinical trial it can never be considered to be the sponsor of the clinical trial.

2.7. Identification of indirect costs (Article II.14.2)

2.7.1. *Methods of calculation of indirect costs (Article II.14.2)*

Participants can opt for one of the following indirect cost methods:

- Actual indirect costs – only for participants who have an analytical accounting system which allows to identify and group their indirect costs (pool of costs) in accordance with the eligibility criteria (e.g. exclude non eligible costs);
- Flat rate of 20% – open to all participants;
- None of the above - only for EFPIA companies when indirect costs are included in the fully loaded FTE rate.

Participant must use the same indirect cost method for all IMI JU projects.

2.7.1.1 *Actual indirect costs*

Participants may opt to report actual indirect costs to the IMI JU according to their usual accounting principles.

The organisations need a fair "key" or "driver" to distribute these costs from the "pool" of indirect costs into the different projects and activities. Different allocation methodologies are acceptable as long as they are in line with the usual accounting and management principles and practices of the participant (i.e. allocation of indirect costs to the project via personnel, either as a percentage of personnel costs or a fixed hourly rate) and they are fair and reliable and not an unsubstantiated estimation. No subjective or arbitrary keys can be accepted.

Where another cost driver not based on personnel is used, the result of the application of this cost driver must not exceed the total amount of indirect costs to be allocated.

Simplified method: 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.

2.7.1.2 Flat rate

The base of calculation is the total direct eligible costs of the participant, excluding the costs of subcontracting and the costs of resources made available by third parties that are not used on the premises of the participant³. In both cases, the overheads (electricity, supply, etc.) are not incurred by the participant but by the subcontractor or the third party.

Example: calculation of indirect costs with a 20% flat rate

- Personnel	1.000.000
- Sub-Contracting	100.000
- Researcher from a third university who works in his university	20.000
- Researcher from a third university who works in the premises of the participant	15.000
- Travel costs	5.000
- Equipment	50.000
TOTAL of Direct costs	1.190.000

Calculation of indirect costs:

$1,190,000 - 100,000$ (subcontracting) $- 20,000$ (researcher who does not work in the premises of the participant) $= 1,070,000 \times 20 \% = 214,000$

2.7.1.3 EFPIA companies having a certified methodology

See Part 3

³ The indirect costs of *consultants doing teleworking* may be reimbursed only in the case of beneficiaries using "actual indirect costs" provided it is their usual accounting practice to allocate indirect costs also to the teleworking hours of consultants. This is not the case for beneficiaries using a flat rate for indirect costs since they are subject to the specific rules of that flat rate. In particular, the flat rate cannot be charged on the costs of resources made available by third parties which are not used on the premises of the beneficiary.

2.8. Summary of cost reporting methods

Reporting methods		Section of reference in these Financial Guidelines	No certified methodology required		CoMAv ¹ Average Pers FP7 certified methodology ==> EC approval		CoM ¹ Average Pers + indirect costs FP7 certified methodology ==> EC approval		Certified methodology ==> to submit to IMI JU	
			Beneficiaries	EFPIA companies	Beneficiaries	EFPIA companies	Beneficiaries	EFPIA companies	Beneficiaries	EFPIA companies
			1	- Direct costs	2.6.1.a)	II.13.1.a)		N/A	N/A	N/A
	- Indirect costs: flat rate of 20% or actual or simplified method	2.7.3 or 2.7.2	II.14.2.a) & b)							
2	- Average personnel costs - Actual other direct costs	2.6.1.b) Option 1 & 2	II.13.1 & 2 if conditions of II.13.2.a) to d) fulfilled deemed not to differ significantly from actual costs		II.13.2 §2 deemed not to differ significantly from actual costs		II.13.2 §2 deemed not to differ significantly from actual costs		N/A	See below
	- Indirect costs : flat rate of 20% or actual or simplified method	2.7.3 or 2.7.2	II.14.2.a) & b)		II.14.2.a) & b)					

3	- Average personnel costs and indirect costs	2.6.1.b) Option 3	N/A	N/A	II.13.2§2 and II.4.5 Option 3	N/A	See below
4	SME owners	2.6.1.d)	II.13.3	N/A	N/A	N/A	
5	"Fully Loaded" or "Partially Loaded" Full Time Equivalent	2.7.4	N/A	N/A	N/A	N/A	II.13.4 and 4.5
Waiving of intermediate Certificate on financial statement (Art. II.4.5)			NO	NO	YES	N/A	YES

1 CoMAv: Certificate on the Methodology on average personnel costs (page 20 of FP7 "Certificates issued by external auditors guidance notes for beneficiaries and auditors")

CoM: Certificate on the Methodology for both personnel and indirect costs for multiple participations in FP7 only (page 16 of FP7 "Certificates issued by external auditors guidance notes for beneficiaries and auditors")

2.9. Suspension of the Project (Article II.8): consequence on eligible costs.

Under the conditions mentioned in Article II.8, the IMI JU may suspend the whole project or parts of the project. Suspending a project has the effect of interrupting the execution of a project to fix specific problems or to re-establish an operational status. Once the reasons for the suspensions are no longer present, the project can – upon the receipt of written confirmation by the IMI JU – continue at the stage reached before the suspension.

During the period of suspension, **no costs can be charged** to the project for carrying out any part of the project that has been suspended. If the IMI JU ends the suspension and allows the project to continue, the remaining project budget can be used under the given rules.

If the suspension leads to a termination of the IMI grant agreement, no further costs can be charged to the project except for costs described in Article II.38.

SECTION 3: THIRD PARTIES, INCLUDING SUBCONTRACTORS

3.1. What is a third party?

A third party is, by definition, any legal entity contributing to the project but which does **not sign** the IMI grant agreement.

A third party may contribute to the project in two possible ways:

- making available its resources to a participant (see section 3.3)
- by carrying out part of the work itself (see section 3.4)

As a general principle, **if the third party not only makes resources available but also carries out work**, then the third party should become a participant by signing the IMI grant agreement unless it falls within the exceptions mentioned below (see section 3.4.1 and 3.4.2, respectively for special clause 4 and subcontractor).

In all cases:

- **the participant retains sole responsibility for the work** of the third party and has to make sure that the third party complies with the provisions of the IMI grant agreement
- the third party, the tasks and the estimation of the costs should be indicated in Annex I.

The table below summarises the different cases and consequences on the IMI grant agreement and reporting obligations:

3.3 Third Parties making their resources available to a participant.			3.4 Third parties carrying out part of the work	
3.3.1. Free of charge	3.3.2 Participant reimburses the third party	3.3.3. Special cases a) Foundations, spin-off companies, etc., not performing technical./scientific work b) Third party authorised to administer on behalf of the managing entity (Special clause 9) c) The case of resources (professors/equipment) working for, or used by a university but whose salaries/costs are paid by the Government. d) Interim or temporary work agency	3.4.1. Subcontractors	3.4.2. Entities covered by special clause 4 -Joint Research Units (JRU) - European Economic Interest Grouping (EEIG) -Affiliates (for beneficiaries only) - Groupings
Actual direct costs	No Profit		Profit margin	
Grant Agreement and Annex I				
Third party, tasks and estimation of costs to be described in Annex I.	Third party, tasks and estimation of costs to be described in Annex I.	For cases a), b) and c): Third party, tasks and estimation of costs to be described in Annex I. <i>For case b): when the participant is the Managing entity</i>	Tasks to be subcontracted and estimation of costs to be described in Annex I	<i>Special clause 4 to be included in the grant agreement</i> Third party, tasks and estimation of

		<p style="text-align: center;"><i>Special clause 9 to be included in the grant agreement</i></p> <p style="text-align: center;">For case d): not mentioned in the grant agreement as it is not considered a third party contribution</p>		costs to be described in Annex I.
Reporting (Form C)				
<p>Costs declared by the Participant in its own Form C, but recorded in the accounts of the third party</p> <p>Declared also as receipts if made available specifically for the project</p>	<p>Costs declared by the Participant in its own Form C, recorded in the accounts of the participant</p> <p>Not receipts!</p>	<p>Costs declared by the Participant in its own Form C, but recorded in the accounts of the third party</p> <p>Not receipts (unless resources made available specifically for the project)!</p>	<p>Form C of the participant under costs category “Subcontracting” of the relevant activity</p> <p>Not receipts!</p>	<p>One individual Form C per third party</p> <p>One summary report integrating cost of the participant and third parties to be provided by the participant (in addition to its own Form C)</p> <p>Not receipts!</p>

3.2. Costs incurred by third parties

As a general rule, the costs are considered eligible cost of a project if incurred by the participants (the signatories to the IMI grant agreement) or in case of EFPIA companies also by their affiliates.

However, in some circumstances, costs incurred by third parties (i.e. any legal entity which does not sign the IMI grant agreement) may also be eligible costs of the project under following conditions:

- the need to include a third party in the project has to be discussed with the IMI Scientific Officer either during the negotiation of the grant agreement, or at a later stage, before the contribution of a third party to the project, thus to be introduced via an amendment,
- if approved, the tasks to be performed, an estimation of the costs and the resources allocated to the project by a third party have to be detailed in Annex I,
- the costs incurred by the third party comply with the eligibility criteria stipulated in Article II.13.

In addition, the third parties, other than subcontractors, carrying out part of the work have to be included in the grant agreement via the special clause 4.

It is important to verify whether the third party contribution is also considered a receipt of the project according to Article II.16 of the grant agreement (see Section 3 of Part 2). If so, it will have to be reported as such in the financial statements (Form C) related to the reporting period in which the receipt has occurred.

If the third party identified in special clause 4 makes also resources available to the participant, the costs incurred by the third party lending resources might be charged by the participant on its own Form C. These costs will be considered receipts if the conditions of Article II.16 are fulfilled.

The IMI JU has the right to audit all the costs originating from third parties.

3.3. Third Parties making their resources available to a participant

Third parties making their resources available to a participant is the case when a participant, while carrying out work for the project, is using one or more resources which belong to a third party while the third party is not involved in the work of the project.

The work is usually (but not exclusively) performed in the premises of the participant.

The contributions made available to a participant must be charged in the Form C of the participant under direct costs. Only the actual direct costs incurred by the third party can be considered eligible costs of the project. In justified cases, e.g. when the resources are made available outside the premises of the participant, the real overheads of the third

party may be also charged by the participant. However, the participant cannot charge a flat rate for the indirect costs incurred by the third party.

The use of flat rates or average rates by the third party is not allowed, even if the third party, when acting as a participant in another EU project, has opted for a flat rate or for average costing of personnel.

3.3.1. Free of charge

This is the case when the third party makes some of its resources available to a participant but does not request any reimbursement from the participant. The costs of the third party will be declared by the participant on its Form C as an eligible cost of the project. They also have to be included in the Certificates on the Financial Statements (CFS) of the participant. Since the resources are made available free of charge, its costs are not present in the accounts of the participant and therefore they **must be recorded in the accounts of the third party** (which can be audited if required). If the resources are made available specifically for a given project, they also have to be declared by the participant on its Form C as receipts of the project.

3.3.2. Participant reimburses the third party

When a participant reimburses the third party, it cannot be considered as a third party contribution. By definition then, these costs will appear in the accounts of the participant, and therefore they will be considered as costs incurred by the participant and not as costs incurred by a third party. In these cases, there is a prior agreement that defines the frame in which these resources are made available and the reimbursement to the third party covers only costs. There shall not be a profit for this third party.

Example:

A legal entity makes available to a participant the use of an installation or specialized piece of infrastructure which the participant needs to perform a project task. There are two possibilities here:

- *The third party charges the costs and is reimbursed by the participant. This is a cost for the participant and not considered as a reimbursement of a third party cost. Details and the reason for the use of the third party should appear in Annex I.*
- *The third party does not charge the participant for this activity; it is not reimbursed by it. If the participant wants to include the cost of the third party as an eligible cost of the project, then the conditions mentioned above for "free of charge" contributions apply. Therefore, the third party who will perform the work, an estimation of the costs and the resources used should appear in Annex I.*

3.3.3. Special cases

(a) Foundations, spin-off companies, etc., created to manage the administrative tasks of the beneficiary

This is typically the case of a legal entity created or controlled by a beneficiary which is in charge of the financial administration of the beneficiary, but which does not perform scientific/technical work in the project (differently from the entities covered by special clause 4). This beneficiary (usually public bodies like Universities/Ministries) has a **prior** agreement with a spin-off company or a separate company/non-profit foundation, by means of which the latter handles the financial and administrative aspects of the participants' involvement in research projects, including all issues relating to the employment and payment of additional personnel, purchase of equipment and consumables, etc. In most of these cases, the aim to improve and rationalise administrative and financial management has led the Universities/Ministries to establish such contracts, which are usually agreements lasting over long periods and established well before the IMI project exists. Consequently, this third party often has no resources of its own. The personnel hired for the project by the spin-off/foundation works on the premises of the University (beneficiary) and under its responsibility. In this case it is the university which should be the beneficiary, and not the foundation, as the foundation does not have the resources to carry out the work⁴.

The agreement is not specific to the project, but it is a general agreement for the management of the IMI grant agreement with the IMI JU (and/or other entities), and the costs are reimbursed either directly by the beneficiary or by the managing entity on behalf of the beneficiary. The costs will therefore not be considered as receipts.

In some cases the agreement between the beneficiary and the third party also foresees the handling of IMI JU financial payments by the third party. Therefore, the managing entity pays the IMI JU financial contribution directly to the third party and not to the beneficiary. As a consequence, in the accounts of the beneficiary there is no trace of any reimbursement from the beneficiary to the third party. In these cases, the important issue is that even though there is no transfer between the beneficiary and the third party, the work of the third party is not carried out without reimbursement, and there is a reimbursement of costs but directly from the managing entity. Thus, the costs will not be considered as receipts. Here the costs of the third party will be charged by the beneficiary in its Form C, but they are recorded in the accounts of the third party (otherwise they would not be eligible).

As these resources are used in the premises of the beneficiary, then the flat rate for the calculation of the indirect costs can be applied to these costs. All reports, financial statements, etc., should be presented in the name of the beneficiary. If a CFS is required, it must certify and cover both the

⁴ If the third party fulfils the conditions set below for the introduction of special clause 4, it may happen also that it carries out itself part of the activities attributed to the beneficiary. In this case, there should be a clear distinction between the contributions made available to the beneficiary, which should be charged under the costs and in the Form C of the beneficiary, and be detailed as such in Annex I, and the work carried out directly by the third party according to special clause 4, which the third party should charge as its own costs under its own Form C.

contributions of the beneficiary and those of the third party. For the costs incurred by the third party and used in its premises, only the real overheads of the third party should be charged. The flat rate of the University DOES NOT apply to these costs since they are not used in the premises of the beneficiary.

Example: Eligible Costs of a University with a 20% flat rate for indirect costs (only in research activities):

- *Costs of personnel (usually permanent) paid by the university* *EUR 100,000*
- *Costs of personnel paid by the foundation and working in the premises of the **university*** *EUR 80,000*
- *Equipment bought by the foundation used on the premises of the beneficiary* *EUR 20,000*
- *Costs of administrative personnel of the foundation working in the premises of the **foundation**: (2.500 EUR actual costs, including EUR 2,000 for direct and EUR 500 for indirect costs)* *EUR 2,000*
- ***total direct costs** (including those of the foundation) = EUR 100,000 + EUR 80,000 + EUR 20,000 + EUR 2,000)=EUR 202,000* *EUR 202.000*

Total costs declared by the university =

- ***total direct costs** : EUR 202,000*
- ***Indirect costs**= calculated on the basis of the direct costs used in the premises of the university+ real indirect costs of the foundation:*
 - *flat rate of 20% of EUR 200,000=EUR 40,000*
 - *+ EUR 500 indirect costs of the foundation*

Total eligible costs: EUR 202,000+ 40,000+500=EUR 242,500

Total IMI JU funding received by the University = 75% of EUR 242,500.

(b) *Third party authorised to administer on behalf of the managing entity (Special clause 9)*

Special clause 9 is to be used when secondary and higher education establishments and public bodies are the managing entity of the project and there is an "authorisation to administer" given to a third party created controlled or affiliated to the managing entity. In this case the costs of this third party are eligible.

This special clause to be requested and approved by the IMI JU refers to cases where:

- secondary and higher education establishments and public bodies **(therefore not to other types of legal entities like companies, etc.)** are managing entities of a project *and*
- a third party controlled or affiliated to the managing entity has got a "mandate" from the managing entity to handle the financial administration on its behalf. Accordingly, this clause allows the managing entity to request that the bank account mentioned in Article 5 is not its own (as established by the IMI grant agreement), but the bank account of the third party created, controlled or affiliated to the managing entity. The introduction of this special clause in the IMI grant agreement allows also the managing entity to delegate to the third party tasks which otherwise are exclusively attributed in the IMI grant agreement to the managing entity (i.e. the tasks mentioned in Article II.2.3 a), b) and c)).

The use of this clause is limited for managing entities, which are public bodies or secondary and higher education establishments that find themselves in one of the situations described above. However, even after the introduction of this clause in the IMI grant agreement, **the managing entity will retain sole responsibility** for the IMI JU financial contribution and for the compliance with the provisions of the IMI grant agreement.

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(c) *The case of governmental resources (professors/equipment) working for, or used by a university*

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In this case the resources made available by the third party (the Government) to the beneficiary can be assimilated to the "own resources" of the beneficiary, and can therefore be charged to the project. They are considered to be a cost of the project because if they were not used for the purpose of the project the participant could use them for other activities. Because the beneficiary is free to use these resources at will they should not be considered a receipt. The third party cost will be declared by the beneficiary in its own Form C. They should be recorded in the accounts of the third party and available for auditing if required.

When these resources/staff have been specifically seconded to the beneficiary to work in a specific project, the costs are eligible but they also need to be declared by the beneficiary as receipts of the project.

Specific "ad-hoc" agreement between a beneficiary and a third party to cooperate in a project. (Example: the use of an installation or the secondment to a beneficiary of a professor from another entity which is not a participant). In this case, if the third party is not working on the project and only lending resources, the general rules for third parties making resources available may apply.

(d) *Interim or temporary work agency*

The case of an "interim" or temporary work agency that makes available staff to a participant: this is **not** a third party contribution because the participant pays the agency for the use of those resources. That use has a price charged to the participant, who will declare it according to its usual accounting practices.

3.4. Third parties carrying out part of the work

Exceptionally the third party performs itself certain tasks of the project, even if it does not sign the IMI grant agreement. The third party **carries out part of the work directly** and is responsible for this vis-à-vis the participant, (the participant remaining responsible vis-à-vis the IMI JU for the work).

IMI JU recognises two different cases of third parties carrying out part of the work:

3.4.1. *Entities covered by special clause 4*

Special clause 4 to be included in Article 7 refers to third parties linked to a participant. **The term "linked" refers to an established formal relationship between a third party and the participant, defined by the following characteristics:**

- This relationship by nature is broad and **is not limited to the IMI grant agreement, or specifically created for the work in the IMI grant agreement.**
- Accordingly, its duration goes beyond the duration of the project and usually pre-dates and outlasts the IMI grant agreement.
- It has a formal external recognition, sometimes in the framework of a legal structure (for example, the relationship between an association and its members), sometimes in the absence of legal personality, through the sharing of common infrastructures and resources (joint laboratory), separate from those of the legal entities composing them, or common ownership (affiliates, holding companies).

"Ad hoc" collaboration agreements between legal entities to carry out work in the project are therefore not covered by this clause; in these cases the legal entities should be participants (with the limited exception of subcontracting in the cases where the rules allow it, as mentioned above).

It is therefore essential to identify these cases during the negotiations and to include the special clause in the grant agreement to allow for the reimbursement of the third parties' costs.

When special clause 4 is used the research work is carried out under the responsibility of the participant.

Third parties covered by the Special clause 4:

- **Joint Research Units (JRU):** these are research laboratories/infrastructures created and owned by two or more different legal entities to carry out research. They do not have a legal personality different from that of its members, but form a single research unit where staff and resources from the different members are put together to the benefit of all. Though lacking legal personality, they exist physically, with premises, equipment, and resources individual to them and distinct from "owner" entities. A member of the JRU is the participant and any other member of the JRU contributing to the project and who is not a participant of the IMI grant agreement has to be identified in the clause. The JRU has to meet all the following conditions:
 - Scientific and economic unity
 - last a certain length of time
 - recognised by a public authority

It is necessary that the JRU itself is recognised by a public authority, i.e. an entity identified as such under the relevant national law. If requested the beneficiary concerned shall be able to demonstrate (during the negotiation or at the time of the addition of the special clause) the relationship existing between the beneficiary and the third party (ies). This could be done by providing any relevant supporting document to this end.

- **European Economic Interest Grouping (EEIG):** an EEIG is a legal entity created under the rules of Council Regulation (EEC) No 2137/85 of 25 July 1985, composed of at least two legal entities from different Member States. In this case the EEIG is the participant and its composing legal entities may be members included in the special clause 4. The contrary (i.e. composing legal entity as participant and EEIG as member in the clause) is not possible.
- **Affiliates of beneficiaries** (affiliates of EFPIA companies identified in Annex I are not concerned): an affiliated entity means any legal entity that is under the direct or indirect control of the beneficiary, or under the same direct or indirect control as the beneficiary. Therefore it covers not only the case of parent companies or holdings and their affiliates, but also the case of affiliates between themselves. However, the entity performing most of the work should be the one appearing as beneficiary, and the others as the members detailed in the clause.
- **Groupings:** The clause is used here either for associations, federations, or other legal entities composed of members (in this case, the grouping is the participant and the members contributing to the project should be listed). In the case of groupings without legal personality they will be treated as JRU if they meet the conditions mentioned above for Joint Research Units. Therefore structures, agreements or units without legal personality created specifically by different legal entities for their participation in the IMI grant agreement are not considered groupings and their costs are not covered under the terms of this special clause. As for EEIGs, it is the association, federation, etc. which should appear as the participant in the IMI grant agreement.

Which conditions have to be fulfilled by these third parties to carry out work and charge costs under the project?

- They have to be identified in special clause 4 and their name, tasks and resources have to be described in Annex I at the same level of detail as participants, since these third parties submit their own Form C.
- Their costs have to comply with the rules and the principles mentioned in Article II.13 to II.16, in the same way as the participants, and must be recorded in their accounts. In other words, the rules relating to eligibility of costs, identification of direct and indirect costs and upper funding limits apply. Equally those concerning controls and audits of Article II.21 and Article II.22.
- Each third party fills in its costs in an individual Form C and, where necessary, shall provide its individual certificate on financial statements. The participant will submit all forms and a summary report integrating both the costs of the participant and those of the third party(ies).

- The threshold of EUR 375.000 for the submission of a certificate on the financial statements applies to the cumulative funding of the participant and its third parties.

3.4.2 Subcontracting (Article II.7)

What is a subcontractor? (Article II.7.1)

As a general rule the participants shall carry out the work for the IMI project employing its own resources. However, as an exception, when the IMI grant agreement provides for it accordingly, certain parts of the work may be subcontracted.

A subcontractor is a type of third party, i.e. a legal entity which is not a participant of the IMI grant agreement, and is not a signatory to it. It appears in the project because one of the participants appeals to its services to carry out part of the work, usually for specialised jobs that it cannot carry out itself or because it is more efficient to use the services of a specialised organisation (e.g. setting up a website for the project).

The subcontractor is defined by certain characteristics:

- "Business conditions": The agreement is based on "business conditions", this means that the subcontractor charges a price, which usually includes a profit margin. This makes it different from other third parties' contributions where the third party charges only for the costs of the activity.
- Responsibility: The responsibility vis-à-vis the IMI JU for the work subcontracted lies fully with the participant. The work that a subcontractor carries out under the project belongs to the participant in the IMI grant agreement. A subcontractor has no rights or obligations vis-à-vis the IMI JU or the other participants. However, the participant must ensure that the subcontractor can be audited by the IMI JU, the European Commission or the Court of Auditors.
- Supervision: The subcontractor works without the direct supervision of the participant and is not hierarchically subordinate to the participant (unlike an employee).
- Working place: The working place of the subcontractor, its accounting rules and internal organisation are also different.
- The subcontractor carries out parts of the work itself
- IPR: Unless otherwise agreed, subcontractors do in general not have any IP rights on the foreground of the project.

The beneficiary shall not subcontract part of the work to its affiliates. These should be identified as third parties linked to a participant and included in the IMI grant agreement via special clause 4.

Accordingly, subcontracting between participants in the same IMI grant agreement is not to be accepted. All participants by definition contribute to and are interested in the project, and where one participant needs the services of another to perform its part of the work, it is the second participant who shall declare and charge the costs for that work.

Subcontracting costs are direct costs. They have to be reported by participants in the financial statement (Form C, Annex V). Like for any costs, the funding rate applicable to subcontracting costs is the funding rate applicable to the type of activity (RTD, etc.) under which the subcontracting costs are claimed.

Selection of subcontractors (Article II.7.2)

Article II.7.2 requires participants to ensure that transparent bidding procedures are used before selecting a subcontractor.

"Any *subcontract*, the costs of which are to be claimed as an eligible cost, must be awarded to the bid offering best value for money (best price-quality ratio), under conditions of transparency and equal treatment."

The procedure to be applied for the award of subcontracts depends on the status of the participant, i.e. if the participant is a public or a private entity:

- Public entities must follow the procurement principles established by their national authorities. For subcontracts exceeding certain amounts, the directive on public procurement of services applies and the publication of a call for tenders is mandatory. **However, they shall in any case comply with the terms of the IMI grant agreement.**

Example:

In an IMI project, a university subcontracts task X for an amount of EUR 50,000. If this amount is below the threshold set by its national public rules (i.e. EUR 100,000), then the subcontract should comply at least with the conditions set out in the IMI grant agreement, even if the national rules do not set out any specific requirement.

- Private legal entities should follow the rules that they usually apply for the selection of procurement contracts, respecting in any case the terms of the IMI grant agreement. The publication of a call for tenders is normally not necessary for private legal entities, but they must at least require submission of several quotes (usually a minimum of three), unless it has an established framework contract for the provision of those services. There should be a proportional relationship between the size in work and cost of the tasks to be subcontracted on the one hand and the degree of publicity and formality of the selection process on the other.

The **procedure must ensure conditions of transparency and equal treatment**. At the request of the IMI JU and especially in the event of an audit, participants must be able to demonstrate that they have respected the conditions of transparency and equal treatment. Participants must be able to prove that:

- the criteria and conditions of submission and selection are clear and identical for any legal entity offering a bid;
- there is no conflict of interest in the selection of the offers;
- the selection must be based on the best value for money given the quality of the service proposed (best price-quality ratio). It is not necessary to select the lowest price, though price is an essential aspect.
- the criteria defining "quality" must be clear and coherent according to the purpose of the task to subcontract, to provide a good analysis of the ratio price/quality.

Framework contracts

Many legal entities have framework contracts with a third party to carry out routine or repetitive tasks (e.g.: an external auditor who periodically audits the accounts of a participant). They have been established before the beginning of the project, and are the usual practice of the participants for a given type of task. These framework contracts can be used to carry out tasks necessary for implementing the IMI project provided they have been established on the basis of the principles of best value for money and transparency mentioned above.

Tasks which can be subcontracted (Article II.7.2)

Subcontracting may concern only certain parts of the project, as the implementation of the project lies with the participants. Therefore, the subcontracted parts should in principle not be major parts of the project work. In cases where it is proposed to subcontract substantial/core parts of the work, this question should be carefully discussed with and approved by the IMI JU and those tasks identified in Annex I. Usually in such cases, the intended subcontractor could instead become a participant, or the consortium should find another participant able to perform that part of the work.

What is a major part of the work?

Subcontracts **shall not concern core research work itself**, but tasks or activities needed to carry out the research, auxiliary to the main object of the project. Subcontracts may involve large amounts of money, even though they have nothing to do with the core parts of the project. Their purpose might be just to facilitate/make possible the research work. In any case, it is recommended that the particular case be discussed with the IMI JU.

Examples:

- *Company "A" needs to subcontract research services to a CRO (Clinical Research Organization). This may consume 20% of the total project cost.*
- *Company "B" needs to collect data and interrogate databases in different countries. That task is subcontracted to a biostatistics services provider for clinical trials*

Management tasks of the coordinator and of the managing entity such as the distribution of funds, the review of reports and others tasks mentioned under Article II.2.3 cannot be subcontracted. Other coordination activities could be subcontracted under the conditions established for subcontracting.

As mentioned above, the participant remains responsible for all its rights and obligations under the IMI grant agreement, including the tasks carried out by a subcontractor. The participant must ensure that the intellectual property that may be generated by a subcontractor reverts to the participant so that it can meet its obligations towards the other participants in the IMI grant agreement. Any bilateral agreement between subcontractor and participant should include this, as well as the respect of the obligations mentioned in Articles II.10, II.11, II.12 and II.21 which concern, among others, obligations related to information and communication of data, and financial audits and controls.

Minor tasks (Article II.7.3)

Minor tasks correspond to minor services, which are not project tasks identified as such in the Annex I but are needed for implementation of the project (quite different from, for instance, analysing samples or conducting CRO studies). They do not have to be specifically identified in Annex I, as by definition their importance is minor (the amounts involved are also normally small). However, the selection procedure mentioned above also applies to these subcontracts.

The criteria to decide whether a subcontract concerns minor tasks are qualitative and not quantitative.

Examples:

- *Organisation of the rooms and catering for a meeting*
- *Printing of material, leaflets, etc.*

Details to be included in Annex I

It is the work (the tasks) to be performed by a subcontractor and the related justification that have to be identified in Annex I. The identity of the subcontractors does not need to be indicated in Annex I. However, even if the identity of the subcontractor is indicated, the participants are nevertheless bound to demonstrate that the selection of the subcontractor complied with the principles described above.

The description of the tasks to be subcontracted should include a financial estimation of the costs. It is also important to have regard to the procedure to be used for the selection of the subcontractor, which should be proportionate to the size of the subcontract.

SECTION 4: Financial contribution made by an EFPIA company to a beneficiary or to participants which are neither a beneficiary nor an EFPIA company (Articles II. 4.1.d) and II.16.c)

4.1. Principles

In a given project, EFPIA companies are allowed to make financial contributions to beneficiaries (academic partners, SMEs) or to participants which are neither a beneficiary nor an EFPIA company (generally not eligible for IMI funding, participating to the grant agreement under special clause 11 - SC11) to reimburse part of their eligible costs. This financial contribution will be considered as part of EFPIA’s in-kind contribution and be recorded as such.

Most likely, this financial contribution will be subject to a bilateral agreement between EFPIA and the beneficiary/participant.

As the objective of the IMI JU is to encourage active public-private partnership, financial contribution should be an exception and should not constitute the majority of the EFPIA in-kind contribution to a project.

The financial contribution **paid by the EFPIA company** should be discussed during the negotiation phase, and at the time of reporting shall be declared by the EFPIA company in its Financial Statement (Form C).

The activities concerned shall be described in Annex I (Section Resource allocation and budget).

The financial contribution **received by the beneficiary/participant** from EFPIA companies:

- must be declared as a **receipt** by the beneficiary(Article II.16) and as a ‘financial contribution’ by the participant SC11(section 3 of the Form C);
- must be used to cover **eligible costs** within the IMI project, i.e. may not be used to cover non-eligible costs (e.g. VAT)
- shall not exceed the amount of the beneficiary/participant 's total eligible costs (Article II.17 (3)).
- may not be paid to third parties (the beneficiary/participant shall directly incur the costs for which it will ask for a reimbursement from an EFPIA company).

The table below shows some examples of financial contribution made by an EFPIA company:

	<u>Financial contribution</u> from an EFPIA company to a beneficiary/participant within the same IMI project. The financial contribution is used by the beneficiary/participant for one of the following :
a) Personnel costs	<ul style="list-style-type: none"> - Personnel on payroll of a beneficiary/participant - Financial contribution from an EFPIA company to cover this personnel costs.

b) Equipment	- Equipment bought by a beneficiary/participant - Financial contribution from EFPIA company to cover depreciation cost of an equipment.
c) Consumables	- Consumables bought by a beneficiary/participant. - Financial contribution from EFPIA company to cover cost of consumables
d) Subcontracting	A situation where an EFPIA company would provide a financial contribution that would then be used by the beneficiary/participant to pay for (part of) a subcontract

4.2. Reporting financial contribution from EFPIA companies

The general principle for reporting the financial contribution in the financial statements (Form C) is the following:

(a) EFPIA companies

How & When: EFPIA companies are required to declare their financial contribution (i.e. actual financial transfers from the EFPIA company to the beneficiary/participant supported by e.g. a separate contract) in the financial statements (Form C) corresponding to the reporting period, i.e. when the financial contribution that has been paid and entered in the accounts.

(b) Beneficiaries/Participants

How: Beneficiaries/participants report in the Financial Statement (Form C):

- as a receipt: the financial contribution made by the EFPIA company;
- as eligible costs: the corresponding actual costs it has incurred (and which have been covered by the financial contribution from the EFPIA company).

Example

An EFPIA company transfers 10.000 EUR as financial contribution to an academic partner. The academic partner uses this funding to buy consumables for the project for an amount of 10.000 EUR (excluding VAT):

- *The EFPIA company declares 10.000 EUR as in-kind (financial) contribution*
- *The academic partner will report:*

10.000 EUR as receipt, i.e. the financial contribution received from the EFPIA company

10.000 EUR as eligible costs for the purchase of consumables (this must be based on actual costs, excluding VAT)

	EFPIA Company	Beneficiary
Eligible costs		10.000 EUR consumables 2.000 EUR Overhead 20%
Financial Contribution	10.000 EUR	
Total Costs		12.000 EUR
IMI JU maximum funding 75 % (*)		9.000 EUR
Receipts		10.000 EUR
Reduced IMI JU funding (*)		2.000 EUR

(*) Since there is a receipt of 10.000 eur, the maximum IMI JU contribution is reduced to 2.000 EUR (total costs 12.000 eur less receipts 10.000 eur). Indeed, [receipts 10.000 + IMI contribution 2.000] may not be higher than [total eligible costs 12.000].

When: Beneficiaries/participants must:

- **declare** receipts which are **established** (revenue that has been collected and entered in the accounts), **generated or confirmed** (revenue that has not yet been collected but which has been generated or for which the beneficiary/participant has a commitment or written confirmation) **at the time of the submission of the periodic report to which they are related to.**
- However, depending on the amount of the receipts compared to total eligible costs, they will be **taken into account** either at the time of the submission of the periodic report to which they are related to (and then the potential reduction of the IMI contribution may take place), or in a subsequent period.

Impact on the IMI JU financial contribution

The table below gives example of the impact of an EFPIA Direct financial contribution on the IMI JU financial contribution.

It is important to remember that the cost declared by the beneficiaries must include the eligible costs of the beneficiary, which are financed by EFPIA.

		EFPIA Funding agreed from the start, BEFORE the grant agreement is signed				Change in ongoing project EFPIA Funding agreed AFTER start date --> increase of eligible costs for Benef.		
		Scenario 1a	Scenario 2a	Scenario 3a	Scenario 4a	Scenario 2b	Scenario 3b	Scenario 4b
		No EFPIA Funding	EFPIA Funding	EFPIA Funding	EFPIA Funding	EFPIA Funding	EFPIA Funding	EFPIA Funding
			No reduction of IMI Contribution	No reduction of IMI Contribution	Reduction of IMI contribution	No reduction of IMI Contribution	No reduction of IMI Contribution	Reduction of IMI contribution
Costs - Beneficiary (Academic or SME)								
(1a)	Total eligible costs:	100	100	100	100	115	125	140
(1b)	including eligible costs incurred by the beneficiary but financed by the financial contribution of an EFPIA company	0	15	25	40	15	25	40
FUNDING - Beneficiary (Academic or SME)								
(2)	Max IMI reimbursement of eligible costs 75% of (1a)	75	75	75	75	86	94	105
(3)	Declaration of receipts (e.g. receipts from an EFPIA company financial contribution) (section 2 of Form c)	0	15	25	40	15	25	40
(4)	Maximum IMI JU requested financial contribution Must be less or equal to (2) and less or equal to [(1a) - (3)]	75	75	75	60	86	94	100
(5)	Beneficiary own contribution	25	10	0	0	14	6	0
Costs – EFPIA company								
(6)	Eligible costs	100	100	100	100	100	100	100
In Kind contribution – EFPIA company								
(6)	Eigible costs	100	100	100	100	100	100	100
(7)	Financial contribution made to beneficiaries (academic, SMEs)	0	15	25	40	15	25	40
(8)	TOTAL in kind contribution	100	115	125	140	115	125	140
TOTAL Project costs (1a) + (6)								
(1a)	Academic, SME	100	100	100	100	115	125	140
(6)	EFPIA company	100	100	100	100	100	100	100
	Total Project costs	200	200	200	200	215	225	240
TOTAL Funding								
(4)	IMI	75	75	75	60	86	94	100
(5)	Beneficiary	25	10	0	0	14	6	0
(8)	EFPIA	100	115	125	140	115	125	140
	Total	200	200	200	200	215	225	240

Notes

(1b) costs incurred by the beneficiary but covered by an EFPIA company may be lower than (3) Receipts from EFPIA if the beneficiary has not yet incurred all the costs

(3) and (7) (3) Receipts from EFPIA declared by the beneficiary must be equal to (7) financial contribution from EFPIA to beneficiary.

(4) Scenario 2b; 3b; 4b: in this scenario, the IMI JU financial contribution increases from 75 to resp. 86 ; 94 or 100. This is however theoretical since the TOTAL IMI JU financial contribution is fixed in the IMI grant agreement and may not increase. Hence, If and INDIVIDUAL IMI JU financial contribution increases for one beneficiary at one period, it must decrease for another beneficiary and/or another period.

(6) Those numbers are totally independent of any EFPIA financial contribution to a beneficiary, as they relate to the activity that EFPIA Company have performed themselves in the project.

SECTION 5: Special case: Donation from an EFPIA company to a beneficiary

This section does not apply to ‘donation of money’, which is considered as a Financial Contribution. It only applies to the physical donation of goods (consumables or equipment). Example: An EFPIA company buys consumables, equipment, etc. and ships them to a beneficiary.

The donation of consumables and equipment is not considered as a financial contribution.

This must be reported as follows:

- The EFPIA company declares the actual eligible costs it has incurred in its accounts. It must be reported in the reporting period when the costs have been incurred.
- The beneficiary does not have to report anything.

Example: consumables purchased by an EFPIA partner (10.000€ excluding VAT) and shipped to a beneficiary:

	EFPIA Company	Beneficiary
	Form C	Form C
Eligible costs	10.000 EUR	0
Financial Contribution	0	0
Receipt	0	0

SECTION 6: Reporting (Article II.4)

Each participant shall submit periodic and interim reports at the date stipulated in Article 4 of the IMI grant agreement.

An "IMI Periodic Report Template" defining the content of periodic reports together with dedicated Q&A are available on the IMI website:

http://www.imi.europa.eu/content/documents#project_documents

6.1. Certificate on the financial statements (Article II.4.4 and II.4.5)

The Certificate on the financial statements (CFS) must be submitted based on the compulsory templates provided in Annex VI – Form D. If the auditor feels however, that one or several of the questions do not correspond to the reality of the accounting system that he/she is describing, he/she should explain this divergence in the form and claim this as an exception. In this case, the IMI JU will consider the explanation based upon the facts provided by the auditor, and decide on its validity.

The IMI grant agreement specifies that these certificates should be prepared and certified by an auditor. This auditor must be independent from the participant. Two cases are possible:

- **The auditor is a qualified auditor**

The auditor must be qualified in accordance with national legislation implementing Directive 2006/43/EC on statutory audits of annual accounts and consolidated accounts 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.

Auditors qualified in the EU could provide certificates for participants established in third countries, but in that case the auditor should be familiar with the relevant national regulations (national accounting rules) of the participants' country and comply with them when preparing the certificate.

- **The auditor is a Competent Public Officer**

The IMI grant agreement foresees the possibility for public bodies, secondary and higher education establishments and research organisations to opt for a competent public officer to provide these certificates, provided the relevant national authority has established the legal capacity of that competent public officer to audit that entity, and that the independence of the officer can be ensured. This does not mean that the above mentioned beneficiaries have to submit automatically and systematically to the IMI JU proof that a national authority has established the legal capacity of a given competent public officer. Neither the IMI JU will systematically ask for such proof unless there are reasonable doubts that the capacity of the competent public officer has not been established correctly.

The IMI JU approval or accreditation is not required and a participant who does not comply with the obligation would be in breach of contract.

Where a public body opts for a competent public officer, the auditor's independence is usually defined as independence from the beneficiary "in fact and/or in appearance". A preliminary requirement is that the competent public officer is not involved in any way in drawing up the financial statements (Form C) and that she/he is not hierarchically dependent from the officer responsible for the financial statements.

Submission of certificate on the financial statements

Certificates on the Financial Statements (CFS) should be provided only once the threshold mentioned in the IMI grant agreement (**EUR 375,000**) has been reached and in any case at the end of the project.

Once a CFS is submitted, the threshold of EUR 375.000 applies again for subsequent IMI JU financial contributions but the count starts from 0.

As mentioned above, a participant can on a voluntary basis submit a CFS before the total requested IMI contribution reaches EUR 375,000. In such a case the counter will be reset for the amount covered by the CFS. However, if a CFS is submitted before the EUR 375,000 threshold is reached, its costs cannot be charged to the project as eligible costs.

Although the threshold is established **on the basis of the IMI JU financial contribution**, the CFS must certify all eligible costs.

Example 1: A participant in a project with duration of 5 years:

<i>Report No</i>	<i>Eligible Costs</i>	<i>IMI contribution at 75%"</i>	<i>Cumulative amount for which a CFS has not been submitted</i>	<i>CFS required</i>	
<i>1</i>	<i>EUR 100,000</i>	<i>EUR 75,000</i>	<i>EUR 75,000</i>	<i>NO</i>	
<i>2</i>	<i>EUR 400,000</i>	<i>EUR 300,000</i>	<i>EUR 375,000</i>	<i>YES</i>	
<i>3</i>	<i>EUR 200,000</i>	<i>EUR 150,000</i>	<i>EUR 150,000</i>	<i>NO</i>	
<i>4</i>	<i>EUR 300,000</i>	<i>EUR 225,000</i>	<i>EUR 375,000</i>	<i>YES</i>	
<i>5</i>	<i>EUR 200,000</i>	<i>EUR 150,000</i>	<i>EUR 150,000</i>	<i>YES</i>	<i>(1)</i>

(1) A certificate is required at the end of the project for any amount not previously certified (Article II.4.4)

It is important to remember that the CFS has to cover the total eligible costs for the concerned periods and not only the amount of requested IMI JU contribution.

Specific case of projects with duration of 2 years or less: a CFS has to be provided only at the end of the project.

Waiver

The requirement to provide a certificate on the financial statements is 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.

- 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.

Specific case of projects having been subject to IMI audit:

If the external auditors contracted by the IMI JU have carried out an audit of the costs incurred by a participant in a given period, the IMI JU can waive the obligation for the certificate on the financial statement for this period. Once the audit has been concluded, the participant's counter will be re-set excluding the audited amount. The CFS will still be obligatory for the costs not covered by previous certificates on the financial statements or audit reports done by external auditors.

The waiver can only be applied in case the audit carried out by the external auditors covered all types of costs, i.e. it will not apply in case of audits targeted only a specific costs, e.g. personnel.

Example: Beneficiary entitled to an IMI contribution of EUR 200,000 in period 1 and of EUR 175,000 in period 2. At that moment it reaches the 375,000 threshold of requested IMI contribution which makes compulsory the submission of a CFS. However, the costs of the first year (justifying the IMI contribution of 200,000) have been audited by the IMI JU. As a consequence:

- the audit will set the counter back to 0 for the first period.*
- if the second reporting period is at the same time the last, there is no need for a CFS for this GA for this beneficiary.*
- if the second reporting period is followed by more reporting periods and the cumulative financial contribution under the form of reimbursement of costs becomes equal to or superior to EUR 375,000, then a CFS would be required, but covering only the costs non-audited by the IMI JU.*

6.2. Approval of reports and deliverables (Article II.5)

At the end of each reporting period, the IMI JU shall

- evaluate and approve project reports and deliverables
- disburse the corresponding payments

within **105** days of the reception of a complete report by surface mail, unless the time limit has been suspended.

Article II.5 provides additional details.

6.3. Adjustments to previous periods

Any adjustment requires the submission of a supplementary Form C for the period, where the details of that adjustment will appear.

Together with the new Form C, the justification and details for the adjustment must be presented by the participant in the periodic report.

Following procedure shall be used for correction of financial statements submitted in previous reporting periods:

1. One Form C for the current period;
2. One separate Form C for every previous period where adjustments are needed, which will include ONLY those adjusted (negative/positive) costs of that specific previous period.

If these costs need to be covered by a Certificate on Financial Statements (CFS), they could be supported within the CFS for the current period but with a specific indication by the auditor certifying both the supplementary costs incurred in previous periods and those claimed in the current one.

Example: In 2009 a participant declared on its Form C, under Research activity, personnel costs incurred in 2009 of €100,000.

In 2010 the participant incurred personnel costs of €120,000. At the same time the participant recalculated its personnel costs incurred in 2009 based on actual figures and found out that the actual personnel costs incurred in 2009 amounted to €99,000.

Reporting in 2010:

The participant needs to submit 2 Forms C in 2010. One Form C declaring 120,000€ of personnel costs incurred in 2010 and another Form C correcting the personnel costs of 2009 in amount of -1,000€ and the appropriate reduction for indirect costs.

6.4. Exchange rates (Article II.6.4)

Participants shall report all their costs in EUR.

- 1) Participants with accounts in currencies other than EUR shall:
 - report the costs on the basis of the exchange rate published by the European Central Bank applied either:
 - on the date when the actual costs were incurred, or
 - on the first day of the month following the end of reporting period.

However, EFPIA companies having a certified methodology for the calculation of the in-kind contribution (see section 1.3 in part 3) shall identify the applicable exchange rate in line with the accepted methodology based on their usual accounting and management principles and practices.

- 2) Participants with accounts in EUR shall convert costs incurred in other currencies according to their usual accounting practices.

The daily exchange rates may be obtained at the following internet address: <http://www.ecb.int/stats/eurofxref/>.

SECTION 7: AUDITS AND CONTROLS

7.1. Financial audits and controls (Article II.21)

7.1.1. Purpose of the audit

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.

FOR BENEFICIARIES ONLY, audit may be also carried out by:

- The European Commission, its own departments – including OLAF – or by any of its duly authorised representatives;
- The European Court of Auditors, by its own departments or by any of its duly authorised representatives.

The audits may cover:

- financial aspects
- systemic aspects
- other aspects such as accounting and management principles.

7.1.2. Participants' rights and obligations

To permit a complete, true and fair verification that the project and the grant are (have been) properly managed and performed, participants are required to:

- keep the originals, or in exceptional cases, where the national legislation accepts or contemplates this possibility, 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.
- ensure that the IMI JU services, and/or any external body(ies) authorised by it, have on-the-spot access at all reasonable times, notably to the participant's offices where the project is being carried out, to its computer data, to its accounting data and to all the information needed to carry out those audits, including information on individual salaries of persons involved in the project. They shall ensure that the information is readily available for on-the-spot checks and, if so requested, that data be handed over in an appropriate form.
- make available directly to the IMI JU all the detailed data that it may request,
- ensure that the rights of the IMI JU, the European Commission and the European Court of Auditors to carry out audits are extended to the right to carry out any such audit or control on any third party whose costs are reimbursed in full or in part by the IMI JU contribution, on the same terms and conditions.

7.1.3. Reports

- A provisional report shall be drawn up on the basis of the findings made during the financial audit and sent to the audited participant.
- The participant may make observations within one month of receiving the report. The IMI JU may decide not to take into account observations or documents sent after that.
- The final report shall be sent within two months of expiry of this deadline.

On the basis of the conclusions of the audit, the IMI JU may recover overstated amounts and apply sanctions including liquidated damages.

7.1.5. Extension of audit findings

Following an audit, the IMI JU services will indicate in the final report whether the possible errors detected during the audit are of a systemic nature, i.e. if they are such that it is reasonable to assume that they affect not only the IMI grant agreement actually audited, but also other IMI grant agreements where the audited entity participates.

If there are errors of systemic nature, the letter of conclusion accompanying the final audit report will require the participants to apply the findings of the audit and to correct the errors in all IMI JU projects by re-submitting within a given deadline the financial statements of all projects where the audited entity participates. These revised financial statements should take into account the conclusions of the audit. The participant will have the possibility of explaining why the audit findings should not be extended to other IMI grant agreements. Should the participant not react, the IMI JU may suspend all payments owed to this participant until the revised cost statements are submitted. Follow-up audits of the participants may be carried out by the IMI JU.

7.2. Technical audits and reviews (Article II.22)

7.2.1. Purpose of the audit

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 technical and ethical audits to be carried out.

- The technical audit may cover:
 - Scientific aspects;
 - Technological aspects;
 - Other aspects relating to the proper execution of the project and the grant agreement.
- The technical audit or review shall assess all the issues stipulated in Article II.22.2.
- The ethics audit shall assess if the project has been carried out in accordance with fundamental ethical principles.

7.2.2. Auditors

Audits may be carried out by IMI JU assisted by external scientific or technological experts.

7.2.3. Participants' rights and obligations

- The IMI JU shall – prior to the evaluation task – communicate the identity of the appointed experts. The participant shall have the right to refuse the participation of a particular external scientific or technological expert on grounds of commercial confidentiality.
- Audit 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 expert may have access to the locations and premises where the work is being carried out, and to any document concerning the work.
- The participant 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 grant agreement.

7.2.4. Reports

- A report shall be drawn up on the outcome of the audits and reviews and sent to the participant.
- The participant may make observations within one month of receiving the report. The IMI JU may decide not to take into account observations or documents sent after that deadline.
- 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 to IMI grant agreement 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 of IMI grant agreement;
 - to recover all or part of the payments made by the IMI JU and to apply any applicable sanction.

SECTION 8: Additional principles for participants which are neither a beneficiary nor an EFPIA companies (special clause 11)

Participants who are neither a beneficiary nor an EFPIA company must declare their direct and indirect eligible costs (Article II.13), by submitting a Form C, in accordance with their usual accounting and management principles.

They are not subject to financial audits.



Innovative Medicines Initiative

PART 2: Additional principles for BENEFICIARIES

SECTION 1: Financial verification of the beneficiaries

Financial verification of beneficiaries is performed by the IMI JU **during the negotiations** and has to be completed before the signature of the grant agreement, (or for later accession, before the approval of the amendment request). All beneficiaries are subject to financial viability check except:

- public bodies;
- natural persons in receipt of scholarships;
- international organisations referred to in Article 43(2) of the Implementing Rules of the EU Financial Regulation;
- Beneficiaries with estimated IMI JU financial contribution inferior or equal to EUR 500,000, except if:
 - the beneficiary is the managing entity of the project and it does not belong to one of the above-mentioned categories; and/or
 - in exceptional circumstances when there are justified grounds to doubt the financial capacity of a participant (e.g.: it has been subject to substantial financial findings following a financial audit in the last 2 years).

If the result of financial verification is "insufficient" financial capacity, the beneficiary cannot participate in the project.

If the result of financial verification is "weak" financial capacity, the beneficiary can participate but, to protect the consortium, the managing entity of the project will be asked to put in place some protective measures including reinforced monitoring of the beneficiary during the implementation of the project.

The managing entity should agree with the beneficiary on protective measures, e.g. dividing the amounts of pre-financing and interim payments in monthly or quarterly instalments and monitoring of the implementation of these measures in a form of monthly or quarterly reports. The IMI JU has to be informed of the protective measures before the signature of the grant agreement.

A beneficiary with weak financial capacity cannot be managing entity of the project unless **the beneficiary, on a voluntary basis, provides the IMI JU with a guarantee which can be considered equivalent to a guarantee by a Member State or an Associated Country**. The financial guarantee should be provided by a bank, an insurance company or by a State.

SECTION 2: IMI JU FINANCIAL CONTRIBUTION

2.1. Upper funding limits for beneficiaries (Article II.15)

The reimbursement of eligible costs must be established following the principles of **co-financing and non-profit**. The upper funding limit fixes the maximum rate of reimbursement of eligible costs per activity and per beneficiary. However, the resulting total IMI JU funding for the project cannot go beyond the maximum IMI JU financial contribution agreed in Article 5 regardless of the total eligible costs of the project.

It is possible for a beneficiary to request a lower reimbursement rate (for instance, to allow another beneficiary to claim the upper funding limit while respecting the maximum IMI JU financial contribution). However, it is not possible for a beneficiary to request lower rate to allow another beneficiary to claim reimbursement beyond the funding limit, even if the maximum IMI JU contribution is respected.

The following upper funding limits are applied in IMI JU projects:

(A) 75% for RTD - Research and technological development activities

RTD activities include

- Activities directly aimed at creating new knowledge, new technology, and products;
- Scientific coordination.

Examples of scientific coordination:

- *The scientific coordination and monitoring of subprojects and work-packages (including the activities as work package leader);*
- *The supervision of project progress milestones and project global critical path;*
- *The scientific review of the work performed by the partners including scientific deliverables and the coordination of internal progress reports;*
- *Monitoring of progress with work packages, deliverables and milestones and the work plan, including the verification of the quality, consistency and respect of deadlines;*
- *Research risk management;*
- *The preparation of the scientific part of the reports and deliverables to be submitted to IMI JU;*
- *Conflict resolving relating to technical and organisational issues;*
- *Preparation by scientific/technical staff of scientific meetings (drawing up the agenda, the minutes..);*
- *Activities related to participation in scientific decision making bodies such executive committees, scientific advisory boards and steering committees (including related travel costs).*

Meetings in relation to the management and coordination of the project should be charged as management activities costs,.

(B) 100% for Management, Training and Other activities

Management activities include:

- Activities stipulated in Article II.2.3;
- Selection process of a subcontractor;
- Preparation of financial reports (including costs of certificates on financial statements).

Management activities can never include "scientific coordination" activities, listed under RTD activities above. Costs related to project meetings (kick-off, periodic, final) should be charged under RTD activities, since they are deemed to address scientific/research aspects of the project.

Examples of Management activities:

- *Designing and maintenance of partner specific templates for collecting input to the required documents,*
- *Implementing and maintenance of a project-specific database for reporting and controlling, including the adaptation of the structure after changes in the work-plan and the consortium,*
- *Drafting and maintenance of the dissemination and exploitation plan following the IMI JU requirements,*
- *Preparing and post-processing of IMI JU reviews from the consortium side including support in the implementation of recommendations from the IMI JU and reviewers,*
- *Preparing, executing and post-processing of major project meetings such as, General Assemblies and meetings with the advisory board (tasks: agendas, invitations, location of meeting places, organisation of rooms and equipment, preparation and distribution of materials, minutes and action lists),*
- *Implementing and maintenance of the project infrastructure, e.g., the internal platform for information exchange and email lists,*
- *Handling of legal issues, IPR issues and maintenance of the project agreement.*
- *Handling of the project correspondence and the day-to-day requests from partners and external bodies.*
- *Organising a call or a tender to choose a new beneficiary or subcontractor*

Training activities include:

- Designing of training programmes
- Organisation of trainings
- Preparation of training material

Training activities are mostly present in Education and Training projects.

Examples of Training activities:

- *Providing the training (salaries of the trainers),*
- *Creation and maintenance of e-portal for web-based training,*
- *Preparation of scope, syllabus and conditions of a training programme (including face-to-face meetings),*
- *Bibliographic research,*
- *Writing, review and analysis of the training materials.*

Other activities

Other activities include activities not covered by the activities mentioned above. They should be discussed carefully during the negotiations, and be **included in Annex I**.

Examples of Other activities:

- ***Dissemination activities*** (e.g. establishment of a website, presentation of the project during conferences or workshops, travel costs related to the presentations, drafting of a scientific publication including, if applicable, the payment of a fee for its publication)
The cost of drafting the first plan for the use and dissemination of the foreground is not an eligible cost since it is a part of the proposal. Only the cost of updating the plan for use and dissemination of foreground is eligible cost of the project. The updated plan forms part of the final report.
- ***Networking activities*** (e.g. organisation of a specific seminar/meeting to network with other projects in the same field); activities aiming at communicating and exchanging information among individuals, groups, etc. outside the project.
- ***Coordination activities*** (e.g. organisation of a meeting or travel for coordination purposes with other projects in the same field).
- ***Intellectual property activities*** (e.g. filing and prosecution of patent (and other IPR) applications, including patent searches and legal advice or the payment of royalties to a third party for intellectual property rights which are needed to implement the project).
- ***Studies on the socio-economic impact*** (e.g. assessment of the expected socio-economic impact of the foreground or analysis of the factors that would influence their use).

2.2. Maximum IMI JU financial contribution (Article 5.1)

The maximum IMI JU financial contribution, stipulated in Article 5.1, cannot be exceeded even if the eligible costs of the project are higher than foreseen in the budget. The payments of the IMI JU financial contribution are made in the following forms:

- a) A single pre-financing payment paid at the start of the project (Article 6)
- b) Interim payments following each reporting period
- c) The final payment at the end of the project for the last reporting period plus any adjustments.

For the calculation of the IMI JU financial contribution, any interest generated by the pre-financing in the bank account of the managing entity as well as any receipt received by the beneficiary has to be taken into account⁵.

2.3. Competitive calls (II. 43)

A "competitive call" is a process to be launched by a consortium of an on-going IMI collaborative research project, after the start of the said project, for the selection of additional beneficiary (ies). This needs to be required by the relevant call for proposals and/or the terms of the Description of Work (Annex I). A portion of the project budget shall have been reserved for specific tasks to be carried out by a new beneficiary (ies) joining the project at a later stage.

The new beneficiaries are therefore selected from proposals submitted in response to a "competitive call". The consortium shall launch such a competitive call and carry out the evaluation under its sole responsibility in accordance with the provisions established in Article II.43. Additionally, to ensure the necessary visibility of the competitive calls to any potential applicants, they will be systematically published on:

- The IMI website;
- The website of each concerned projects
- The FP7 Participant Portal⁶:

The consortium is assisted by at least two independent experts appointed on the basis of the criteria described in the IMI Rules for submission, evaluation and selection of expressions of interest and full project proposals.

At the end of the process the consortium submits a request for amendment to IMI JU in order to request the accession of the new beneficiary (ies), in accordance with Article II.35. In doing so, it will also provide the IMI JU with the necessary information about the entire process: how the competitive call was launched and carried out, including details about experts involved in the evaluation.

The costs for the implementation of the "competitive call" (such as publication of the call, remuneration of the experts etc.) are eligible costs of the project.

⁵ For information on interest yielded by pre-financing, see Article II.18. For receipts, see Article II.16. See also below section 3 Receipts and Interests.

⁶ <http://ec.europa.eu/research/participants/portal/page/othercalls/competitive>

SECTION 3: RECEIPTS AND INTEREST

2.1. Receipts of the project (Article II.16)

2.1.1. Principles

The IMI JU financial contribution may not have the purpose or effect of making a profit for the beneficiaries. For this reason, the total accepted IMI JU financial contribution plus receipts cannot exceed the total eligible costs.

Three kinds of receipts must be taken into consideration by beneficiaries:

- Income generated by the project.
- Contribution in-kind or financial transfers or their equivalent from third parties
- Financial contribution from EFPIA companies and their affiliated entities or from participants which are neither beneficiary nor an EFPIA company

Receipts are assessed and accounted for at the level of a beneficiary. If the total IMI JU financial contribution + receipts \leq total eligible costs \rightarrow No reduction of the IMI JU financial contribution

Example: Impact of receipts (other than EFPIA financial contribution, see table under part 1 section 4.2) on the IMI JU financial contribution

Eligible costs: 100, IMI JU financial contribution: 75, receipts: 25 \rightarrow no impact

Eligible costs: 100, IMI JU financial contribution: 75, receipts: 20 \rightarrow no impact

Eligible costs: 100, IMI JU financial contribution: 75, receipts: 35 \rightarrow the IMI JU financial contribution will be reduced by 10 to 65

It is recommended to include an estimated amount of receipts in the budget of the beneficiary during the negotiation stage (if possible).

2.1.2. Income generated by the project

Any income generated by the project, including the sale of assets bought for the project (limited to the initial cost of purchase) is considered as a receipt of the project (e.g. admission fee to a conference carried out by the consortium, sale of the proceedings of such a conference, sale of equipment bought for the project, etc.).

By derogation to the above-mentioned principle, income generated in using the foreground resulting from the project is not considered as a receipt.

2.1.3. Contribution in kind or financial transfers or their equivalent to the beneficiary from third parties

There are two cumulative conditions to be fulfilled to consider these endowments as receipts of the project (Article II.16):

- If the contribution is made by a third party specifically for the purpose of the project, the resources must be declared as receipts of the project in the beneficiary's Financial Statement (Form C). However, if the use of these contributions is at the discretion of the beneficiary they are not to be considered as receipts of the project.
- If there is no full reimbursement by the beneficiary to the third party, the part of the costs that has not been reimbursed has to be considered as a receipt and must be declared by the beneficiary as such. The part which has been reimbursed is a cost to the beneficiary, and should be declared as such.

Example:

A university professor whose costs are charged by the university in the grant agreement, but whose salary is paid by the Ministry. This in kind contribution from a third party (the Ministry) is not a receipt of the project, unless the professor has been specifically detached by the Ministry to the university to work for the project in question. In other words, if the University is free to decide the allocation of the professor's work, then his/her contribution is not considered a receipt of the project.

Where contributions from third parties are used by the beneficiary for the project, the latter is required to inform the third party of this use, in accordance with the national legislation or practice in force.

2.1.4. When to declare receipts from third parties (other sources than EFPIA)?

Beneficiaries must declare receipts which are established (revenue that has been collected and entered in the accounts), generated or confirmed (revenue that has not yet been collected but which has been generated or for which the beneficiary has a commitment or written confirmation).

Receipts from third parties other than EFPIA company should be declared on the beneficiary's financial statement (Form C – point 2b) corresponding to the period during which they were incurred. They will be taken into account for the calculation of the accepted IMI JU financial contribution by IMI JU at the end of the project.

2.1.5. When to declare receipts from EFPIA companies?

See Part 1, Section 5.4

2.2. Interest yielded by the pre-financing (Article II.18)

2.2.1. When to declare interest?

Article II.18 refers to the obligation to deduct the interest generated by the pre-financing from the payment of the amounts due to the beneficiary when such pre-financing exceeds EUR 50,000 (Article 104 of the IMI Financial Rules).

This rule applies only to the pre-financing, and not to interim payments.

2.2.2. How to declare interest?

The managing entity (and only the managing entity) shall declare the interested yielded by the pre-financing on its financial statement (Form C – point 3). To avoid discrimination between beneficiaries, the managing entity shall declare interest only from the share of pre-financing not distributed to the other beneficiaries of the project. This means that the managing entity does not have to declare interest on its own part of pre-financing.

In case the pre-financing is not fully distributed among beneficiaries during the first reporting period, the managing entity shall declare the interests generated for all reporting periods until the full distribution of the pre-financing.

The IMI JU will offset the interest against subsequent payments.

Example: 5-year project:

The managing entity receives a pre-financing of EUR 1,600,000 for the whole duration of the project and retains for itself the agreed amount corresponding to its share of the pre-financing: EUR 400,000, in compliance with the Project agreement signed by all beneficiaries.

In this case, the managing entity will declare the interest generated by the pre-financing of EUR 1,200,000 until the moment of its transfer to the other beneficiaries.

At the end of the reporting period the managing entity has to declare the amount of interests yielded by the pre-financing in its financial statement (Form C). The IMI JU will deduct the amount of interest from the subsequent interim payment.

SECTION 3: PAYMENT MODALITIES AND TIME-LIMIT

3.1. Bank account (Article 5.3)

It is recommended that the bank account included in the IMI grant agreement (i.e. the bank account of the managing entity⁷) is used exclusively for handling the project funds. The reason being that, to fulfil its obligations, the managing entity must, at any moment, be able to identify dates and figures related to any payment received or made under the IMI grant agreement (Article II.2.3).

This requirement is important for audit and control purposes (i.e. to enable a reconciliation of accounting records with the actual use of funds).

In any case, if an existing account/sub-account is used, the accounting methods of the managing entity must make it possible to comply with the above mentioned requirements.

3.2. Pre-financing at the start of the project (Article 6)

There is only one pre-financing payment (advance payment) during the life of the project. It is received by the managing entity at the beginning of the project and in any case within 45 days of the entry into force of the grant agreement (unless a special clause stipulates otherwise). The managing entity distributes it to the other beneficiaries:

- Following instructions from the coordinator
- Only to those beneficiaries who have signed and returned Form A and only after the minimum number of participants have acceded to the grant agreement (i.e. one beneficiary and one EFPIA company).
- In accordance with the IMI grant agreement and the Project Agreement.

Like any other payment, the managing entity has to be able to determine at any time the amount paid to each beneficiary (and inform the IMI JU of this when required).

The pre-financing remains the property of the IMI JU until the final payment.

The amount of pre-financing is defined during the negotiations, but as an indicative general rule, for projects with duration of more than two reporting periods, it should be equivalent to 160% of the average IMI JU funding per period. However the amount of the pre-financing may change in cases where the specific circumstances of the individual project require it.

⁷ Except when the introduction of Special clause 9 in the GA allows for the managing entity to request that the payment of the IMI JU contribution is made on a third party's account. For a list of all special clauses see the IMI Website.

3.3. Interim payments following the approval of periodic reports (Articles II.5 and II.6)

Interim payments are made on the basis of the accepted eligible costs and the corresponding reimbursement rates as indicated in Article II.15 of IMI grant agreement. The amounts paid as interim payments correspond to the accepted IMI JU contribution. However, the total amount of interim payments + pre-financing is limited to 90% of the maximum IMI JU financial contribution. This implies that in some cases an interim payment may be reduced to respect this limit.

Example:

Project duration: 5 years

Maximum IMI JU contribution: EUR 5.000.000

Pre financing: EUR 5.000.000 / 5 periods x 160 %

Ceiling: EUR 4.500.000 (10% retention)

	<i>Accepted IMI JU financial contribution: EUR</i>		<i>Cumulative payments(EUR)</i>
<i>Period 0</i>		<i>Pre-financing 1,600,000</i>	<i>1,600,000</i>
<i>Period 1</i>	<i>1,000,000</i>	<i>Interim payment P1 1,000,000</i>	<i>2,600,000</i>
<i>Period 2</i>	<i>800,000</i>	<i>Interim payment P2 800,000</i>	<i>3.400.,000</i>
<i>Period 3</i>	<i>900,000</i>	<i>Interim payment P3 900,000</i>	<i>4.300.,000</i>
<i>Period 4</i>	<i>800,000</i>	<i>Interim payment P4 200,000 To respect the ceiling</i>	<i>4.500.,000</i>
<i>Period 5</i>	<i>1.500.000</i>	<i>Final Payment</i>	<i>500.000</i>

3.4. Final payment following the approval of final report (Articles II.5 and II.6)

The final payment is made after the approval of the final reports and consists of the difference between the accepted IMI JU financial contribution (on the basis of the eligible costs) minus the amounts already paid.

The total payment is however limited to the maximum IMI JU financial contribution as stipulated in Article 5. If the total amount already paid would prove to be higher than the accepted IMI JU contribution, the IMI JU will recover the difference.

3.5. Time-limit for payments (Article II.5)

At the end of each reporting period, the IMI JU shall evaluate and approve periodic reports and deliverables and disburse the corresponding payments within **105** days of their receipt.

Any suspension of the time-limit, payment or the project is not included in this time limit.

SECTION 4: RECOVERY AND REIMBURSEMENT (Article II.20)

IMI JU may request beneficiaries to reimburse amounts which are paid to them for example by mistake or when at the end of the project the accepted IMI JU financial contribution is lower than the amounts previously paid to a beneficiary in a form of pre-financing and interim payments.

IMI JU may also recover from beneficiaries amounts which were found non-eligible during ex-post audits.

If, following a request from the IMI JU, a beneficiary does not reimburse any requested amount within 30 days after receipt of the request, the IMI JU shall recover the amount due by the said beneficiary by any appropriate means, including invoking any guarantees.

SECTION 5: SANCTIONS

5.1. Liquidated damages (Article II.23)

The IMI JU shall claim liquidated damages⁸ from a beneficiary who is found to have overstated expenditure and who has consequently received an unjustified financial contribution from the IMI JU. Liquidated damages will be applied systematically by the IMI JU in case of overstatement.

Overstatement may result from errors, misunderstanding or misinterpretation of the provisions of the IMI grant agreement. Overstatement is a factual finding and the intention to overstate is irrelevant.

Liquidated damages are calculated according to the rules stipulated in Article II.23.2.

⁸ In exceptional cases, the IMI JU may refrain from claiming liquidated damages.

Example of liquidated damages calculation:

The eligible costs declared by a beneficiary amount to EUR 1.000.000 (for a project funded at a 75% rate) and the IMI JU financial contribution claimed for that period was EUR 750.000. During an audit, it was found to have overstated costs for an amount of EUR 400.000 and to consequently have received an unjustified financial contribution from the IMI JU of EUR 300.000.

*The amount of liquidated damages the IMI JU shall claim is:
EUR 300.000 x (EUR 400.000 / EUR 750.000) = EUR 160.000*

Modalities

Liquidated damages are due in addition to the recovery of the unjustified financial contribution from the beneficiary.

Example:

If liquidated damages are applied to the beneficiary mentioned in point 1, that beneficiary will have to reimburse to the IMI JU the total amount of:

- *Unjustified financial contribution* (a): EUR 300.000
- *Liquidated damages* (b): EUR 160.000
- *Total amount* (a) + (b): EUR 460.000

To respect the contradictory principle, the beneficiary shall be given a written notice period of 30 calendar days to provide the IMI JU with its observations (Article II.23.3).

Cases where liquidated damages may not be applied

In exceptional cases, the IMI JU may refrain from claiming liquidated damages. The IMI JU may decide in duly justified cases and if appropriate under the principle of proportionality not to request liquidated damages. The following cases could be considered:

- a) When the consortium submits financial statements at the end of a period and the IMI JU corrects an overstatement of expenditure before the payment. In this case there would be no grounds for liquidated damages, as the subsequent IMI JU payment would not have taken into account any overstated amount. Here the beneficiary would not receive any unjustified financial contribution.
- b) When the IMI JU makes an interim payment following a financial statement submitted at the end of a period, but the financial statement is later corrected by the beneficiary at its own initiative. When the beneficiary modifies a previous financial statement, liquidated damages should not be applied. If however it is the IMI JU who finds the overstatement following the payment, liquidated damages will be applied.

- c) When, following an audit in a particular project, a beneficiary at its own initiative corrects costs declared within the framework of other projects (extrapolation). In this case, the IMI JU could decide not to apply liquidated damages.

5.2. Financial penalties (Article II.24)

In addition to liquidated damages, any beneficiary found to have seriously failed to meet its obligations under the IMI grant agreement shall be liable to financial penalties of:

- between 2% and 10% of the value of the IMI JU financial contribution received by that beneficiary under the grant;
- between 4% and 20% of the value of the IMI JU financial contribution, received by that beneficiary, in the event of a repeated offence in the five years following the first infringement.

Example:

It is determined that a beneficiary has seriously failed to meet its obligations under the IMI grant agreement.

According to the information from the managing entity, the beneficiary has received an IMI JU financial contribution of EUR 700,000.

According to the audit's findings, it is the first serious failure of this beneficiary in actions supported by the IMI JU in the last five years.

This beneficiary may be subject to additional financial penalties of between EUR 14,000 and EUR 70,000 = (2%-10%) of EUR 700,000.

This is in addition to the recovery of the amount overpaid (unjustified financial contribution) and the liquidated damages for overcharging.

The provision also applies to beneficiaries who have been guilty of making false declarations. In both cases, the beneficiary will also be excluded from all grants financed by the IMI JU for a maximum period of two years from the date the infringement is established.



Innovative Medicines Initiative

PART 3: Additional principles for EFPIA COMPANIES

SECTION 1: IN-KIND CONTRIBUTION

1.1. Definition and general principles of in-kind contribution

Costs incurred by research-based pharmaceutical companies that are members of EFPIA are considered as in kind-contribution to the project. They will be calculated under the conditions laid out in the IMI grant agreement (Article II.4.1 and II.13.4).

In-kind contribution of EFPIA companies shall be duly described in the Annex I of the IMI grant agreement (Description of Work) for each IMI project (including the timeframe of that contribution).

At the time of the evaluation, in kind contribution

- shall be the total value of resources (human, equipment, financial contribution, etc.) involved in IMI projects by EFPIA participants. Resources declared shall always be those effectively involved in the related project;
- shall normally be counted only for prospective research conducted in Europe and FP7 associated countries (unless a special clause for the acceptance of *Non-EU in-kind* contribution applies, see next section below) during the duration of the project;
- will be calculated and reported according to their usual accounting and management principles and practices;
- shall be reported by each EFPIA participant (including its affiliates) and per project.

By default, EFPIA companies shall abide to principles and rules applicable to IMI beneficiaries except if otherwise specified.

Most EFPIA companies will calculate and report in kind contribution as described in their certified methodology (Article II.13.4), further details in Section 1.3 in this Part 3. Those companies not having a certified methodology will follow the principles described in earlier sections of this document.

Non-EU in-kind contribution

As a general principle, costs incurred by research based pharmaceutical companies that are members of EFPIA for the project outside European Member States or countries associated to the Seventh Framework Programme can only be acknowledged as in-kind contribution, but will not be counted towards the matching IMI JU financial contribution.

However, on a case-by-case basis non-EU EFPIA in-kind contribution can be accepted and therefore calculated as part of the EFPIA in-kind contribution.

This requires the inclusion in the grant agreement of a special clause (13 –a or b).

The acceptance of non EU in kind as eligible in kind contribution is done as follows:

- a. For standard projects (special clause 13.a): A limit of 10% per IMI collaborative research project within a global cap of 5% at programme level of the actual committed EFPIA in-kind contribution to research activities may apply when agreed at the time of the selection decision of full project proposals.
- b. For special projects(special clause 13.b): For topics of interest for EU citizens that will benefit European academics and SMEs, where there are few EFPIA research capacities in Europe while academic research is strong or substantially developed in Europe and, in particular research into rare diseases or disease areas of high public interest where creation of a critical mass of research is needed, a global cap of 30% at programme level of the actual committed EFPIA in-kind contribution to research activities, with no limit per IMI collaborative research project, may apply when agreed at the time of the Call definition and confirmed at the time of the selection decision of full project proposals

The overall allocation of the ‘Non-EU in-kind’ is a strategic decision which may affect other projects and/or Calls, it needs therefore to be prior coordinated and agreed by the Research Directorate Group among the EFPIA companies.

For further information, please see Annex II- *Non-EU EFPIA in-kind contribution*.

1.2. Indicatives types of eligible in-kind contribution

The vast majority of the in-kind contribution will be by allocating skilled personnel (whose cost may be calculated using a FTE rate) to IMI projects. Companies shall follow their normal accounting standards on how to calculate the FTE cost, if applicable and most will apply a method of using average FTE costs (rates). In addition, other direct costs not included in the average FTE rate may be added.

For a detail of eligible costs, please refer to Part 1-section 2.5 Identification of direct costs

1.3. Methodology for calculating the in-kind contribution

EFPIA companies will calculate and report their in-kind contribution according to their usual accounting and management principles and practices. EFPIA companies may opt to declare actual cost or average personnel costs.

In both cases – actual costs or average personnel costs, EFPIA companies will use validated time tracking system to record time spent on research projects. Only the hours worked on the project can be charged. Working time to be charged must be recorded **throughout the duration of the project by time sheets**, adequately supported by evidence of their reality and reliability.

For further information on time sheets, see Part 1- section 2.5.1. Direct costs

In the absence of time sheets, the EFPIA company must substantiate the cost claimed by reasonable means (alternative evidence) giving an equivalent level of assurance.

Please refer to Part 1- Section 2.5.1 Cost of personnel assigned to the project.

Depending on the characteristics of the EFPIA company and/or on the operation in question, it is possible that some costs can be considered either **direct** costs or **indirect** costs, but no cost can be taken into account twice as a direct cost and as an indirect cost. Please also refer to Part 1- Section 2.5 direct costs and Section 2.6 indirect costs.

In some EFPIA companies, the standard average FTE rate may already include costs for general consumables, plus indirect costs. Companies that already include indirect costs in FTEs and in "Fully-loaded" FTE may not claim the 20% indirect costs on top, as this would result in a double charging for indirect costs.

As a reminder indirect costs apply to all direct costs except sub-contracting costs and except costs of third parties incurred outside premises of the EFPIA company.

1.3.1. Actual costs

This approach is based on actual costs incurred for the project without using any FTE average rate calculation for the direct costs reporting (See Part 1).

This methodology does not require a certificate on in-kind contribution methodology to be submitted to IMI (nor to be certified by external auditors). In this case, there is no waiving of the requirement to provide a certificate on the financial statement (Article II.4.5). Precise conditions for when the submission of the CFS is waived see Section 2.6.1.b) and Section 6.1).

1.3.2. Average personnel costs

EFPIA companies may also declare average personnel costs under the conditions described in Part 1 if consistent with the management principles and accounting practices of the EFPIA company.

1.3.3. Certified methodology on in-kind contribution (Article II.13.4)

EFPIA companies which are not using actual personnel costs, may opt to describe, before the start of a project, the methodology used to report their in-kind contribution, including average personnel costs (including FTE rate).

Certification

A standard template '*Certification on in-kind contribution methodology*' must be used by EFPIA companies. This template must be certified by an independent auditor and should be submitted only once for all IMI JU projects, unless there is a change in the company's methodology.

This certification should assess the accounting methodologies (e.g. average personnel costs) used by the EFPIA company.

An EFPIA company should use the same methodology throughout IMI unless the methodology is changed by the company.

- for IMI JU projects and other research projects: the methodology should be used by the concerned EFPIA company in similar non-IMI research activities, for example in a research project.
- over time, *i.e.* from the moment an investment decision is planned, until the report and certification of the costs of a project (in other words. from the moment they provide their indicative in-kind contribution for the call publication and for the drafting of the full project proposal, till the cost reporting in a project).

If different methodologies are used within a company, the company must specify that the one submitted to IMI JU will be the same as the one used for the reporting the certified accounts.

There are basically two main methodologies:

a) FTE rate booked in the accounting system

With this methodology, the FTE rate is booked in the accounting system (i.e. the FTE rate is actually booked on the project code in the analytical accounting). The total in-kind contribution will be directly extracted from the accounting system:

- A. standard FTE rate is calculated based on the costs, as registered in the statutory accounts and the EFPIA normal internal procedures
- B. Rigorous time recording of individuals per IMI project: time registered in the time keeping system is (automatically) transferred to the accounting system and multiplied by the FTE rate.

- C. Other specific direct costs not covered in the FTE rate are accounted for to the IMI projects in the accounting system.
- D. Indirect costs: depending on the company usual accounting principles, indirect costs are already included in the FTE rate or accounted for separately.

Total contribution is calculated as $(A \times B) + C + D$

With this methodology, the analytical system (project code) provides a full overview of the in-kind contribution as the FTE rate and the direct costs are charged on the project code.

b) FTE rate derived from the costs of the EFPIA company

In this methodology, FTE rate is based on the costs of the EFPIA Company as registered in its statutory accounts. However, there is no automatic link between the time keeping system and the accounting system; hence there is no direct booking of FTE rate on the IMI project code in the accounting system.

With this methodology, the reporting of the in-kind contribution will be calculated as follows:

- A. Standard FTE rate is calculated based on the costs, as registered in the statutory accounts and the EFPIA company's normal internal procedures.
- B. Rigorous time recording of individuals per IMI JU project: time registered in the time keeping system. However in this methodology there is no direct link between the time keeping application and the account system (i.e. the computation, time x costs is done in separate system).
- C. Other specific direct costs not covered in the FTE rate are accounted for to the IMI projects in the accounting system.
- D. Indirect costs: depending on the company usual accounting principles, indirect costs are already included in the FTE rate or accounted for separately.

Total contribution is calculated as $(A \times B) + C + D$, but this reconciliation is usually done manually when there is no automatic link between $A \times B$ (time keeping) and C (accounting).

Standard FTE Rate

Please refer to Part 1 – section 2.5.1 b).

FTE rate may include cost **outside the EU** provided that only research costs incurred in Europe (Member States and countries associated to FP7) are reported to the project.

SECTION 2: Reporting for EFPIA companies (Article II.4)

See Part 1 – section 5

The annual financial reporting includes

- A financial statement (Form C)
EFPIA must submit one Form C per period, for each project. The in-kind contribution from an EFPIA company and its affiliates may be aggregated and declared in one single Form C per period (provided that the EFPIA company and the affiliates use the same methodology).

- Certificate on the Financial Statement (CFS), established by an independent auditor (if contribution is over 375.000 EUR in a given project).
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 (Article II.4.5).

ANNEX I – Frequently Asked Questions (FAQ)

Eligible costs

1. Can costs related to the drafting of the Full Project Proposal be eligible?
See Part 2 – section 2.3
2. Can cost of consumables incurred before start date of the project be considered as eligible?

Examples: Clinical samples or compounds pre-existing to the project, but which would be entirely used for the sole purpose of the specific IMI JU project.

Based on scientific or technical justification and with the prior agreement of IMI JU (i.e. Governing Board decision), some consumables (such as compounds or samples) entirely used up during the implementation of and for the sole purpose of the specific IMI JU project may be exceptionally considered in relevant cases. The need for using such consumables has to be stated -together with the related value- in the Call text and/or in the Full Project Proposal (the FPP).

When not entirely used up, remaining sample or compound should be returned to the originator or, upon IMI JU approval, used up for other purposes. In such cases, any significant impact on original in-kind value must be discussed with IMI JU.

Such consumables shall be valued and recorded according to the usual accounting and management principles and practices of the participant, including the possibility to base the value on replacement costs, and auditable. The in kind value can either be based on:

- replacement cost of the specific consumables in question as documented by specific quotes or
- a value of comparable consumables as justified by the specific EFPIA company's historic quotes/purchases over the last 1-2 years or
- a value of comparable consumables as justified by historic quotes/purchases over the last 1-2 years of one of the EFPIA companies involved in the project. This option can only be used at project level.

The EFPIA company providing the value of the consumables for the project has to keep all supporting documents for audit purposes and provide them to other EFPIA companies on auditor's request.

See Part 2 – section 2.3

Time & personnel

3. How do I record **time** spent on IMI projects?
How can I track IMI **time** contributions?
See Part 1 - section 2.6.1. Personnel costs

4. Are **training** costs able to be included?
Yes for personnel costs of those providing the training (but personnel costs for time spent in attending the IMI JU lecture courses for those being trained is not eligible).
5. If I have to travel for IMI activities can I charge **travel** & subsistence costs?
See Part 1- Section 2.6.2.Travel and subsistence allowances for staff taking part in the project
6. Can a PhD student be funded by industry while working in an academic laboratory?
Yes, *see Part 1- Section 4 – Financial contributions made by an EFPIA company*
7. Can we set an average FTE rate for all partners in the project?
What if my company's FTE calculation is different from that of other participants in my consortium?
All EFPIA companies must follow their own accounting principles (*see Part 3*)

Other costs (equipment, consumables, samples, data)

8. How can I assign value to use of **equipment**?
See Part 1 - section 2.6.3.Equipment
9. What costs can I assign for **consumables**?
See Part 1 - section 2.6.4.Consumables
10. What costs can be assigned to **IT hardware & software**?
See Part 1 - section 2.6.3.Equipment
11. What sort of **animal** costs can be included?
See Part 1- section 2.6.9.

Subcontracting, audit, cash transfers

12. What if I need to **subcontract** specific parts of the project work?
Can I subcontract some services to other members of the consortium? Here the answer is categorically no!
See Part 1- section 3.4.2 Subcontracting
13. Can the IMI-JU or EU Commission perform an **audit** of the company?
For Beneficiaries, *See Part 2 - section 5. Audit*
For EFPIA companies, *See Part 3 - section 3. Audit*
14. Can EFPIA companies provide **financial contribution** rather than in-kind contributions?
See Part 1 - section 4 Financial contribution made by EFPIA companies

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ANNEX II – Non-EU EFPIA in-kind contributions

Summary of the IMI Governing Board decision:

To recognize non-EU EFPIA in-kind contributions as matching contributions, i.e. 1) for **standard projects** a limit of 10% per IMI collaborative research project within a global cap of 5% of the actual committed EFPIA in-kind contributions and 2) for **special projects** (defined below) a global cap of 30% of the actual committed EFPIA in-kind contributions.

Modalities:

	Special clause 13 a Standard projects	Special clause 13b Special projects
Scientific areas	Any IMI project	Defined as projects: (a) of interest to EU citizens that will benefit European academics and SMEs, and (b) for which there are limited EFPIA research capabilities in Europe while academic research is strong or substantially developed in Europe, in particular research (rare diseases or disease areas) of high public interest on which research critical mass is needed
Scope	For all new projects and on-going projects - special clause 13a or 13b for inclusion or subsequent amendment in the Grant Agreement	
Basis for calculation	The total sum of all actual committed EFPIA in-kind contributions. Thus, when a subsequent Call is approved for launch by the IMI Governing Board, the sum available increases based on the actual committed EFPIA in-kind contributions to the new Call.	
Ceilings	Maximum: 10% of EFPIA committed in-kind contribution per project; within a global cap of 5% of the actual committed EFPIA in-kind contributions of entire research programme in the IMI-JU.	Maximum: 30% of the actual committed EFPIA in-kind contributions of the entire research programme in IMI-JU; no limit at project level
	Both special clauses can be applied in parallel, but have to be within the given caps	

<p>Examples on Simulation Actual vs. Maximum</p>	<p><i>The following example is based on € 500 M of total actual committed in kind in all launched Calls</i></p>	
	<p>1) For all Calls A) Maximum available non-EU in kind for standard projects (5% of 500): € 25M B) Effectively used⁹: €22 M C) Remains for remaining calls € 3M (A-B)</p> <p>2) New project in a new Call In kind commitment to project X = € 50M, 5% of €50M = €2,5M</p> <p>Non-EU in kind available for project X = 5% of in kind for project X + unused non-EU in kind previous calls (C) In this case = €2,5M + €3M = €5,5M</p> <p>But maximum cap per project is 10%, ie for project X maximum € 5 M is available.</p>	<p>1) For all Calls D) Maximum available non-EU in kind for special projects (30% of 500): €150 M E) if applying B) in parallel maximum available for special projects would be : € 150M minus, what is used in standard projects, i.e. €150M – € 22M = €128M</p> <p>2) New special project in a new Call Total actual commitment for project Y = € 550M 30% of €550M = €165M</p> <p>Effectively used non-EU in kind already in standard projects = € 27M (€ 22M for all previous Calls + €5M for project X) Maximum available for special projects: 165 - 27 = €138M</p> <p>Alternative: maximum for new special project and nothing for new project X, ie 165 minus previous non-EU in kind from previous Calls ie 22m = €143M available</p>
<p>Decision making process</p>	<p>The EFPIA Research Directorate Group (RDG) is responsible for the decision on the overall allocation, ie the strategic plan; and this plan will be submitted to the IMI Governing Board, by EFPIA on an annual basis¹⁰</p>	
<p>When?</p>	<p>At the time of the selection decision of the Full Project Proposals for funding or when appropriate for ongoing projects (based on a valid reason)</p>	<p>At the time of the Call definition Confirmed at the time of the selection decision of the Full Project Proposals for funding</p>

⁹ Means effectively committed at the moment of the grant agreement signature. The amount of non-EU and EU in kind contribution effectively reported by EFPIA companies and accepted by IMI Executive office will have to be communicated to the Governing Board on a regular basis by the Executive Office in order to monitor the remaining amounts of non EU in kind contribution that could be reported by EFPIA companies.

¹⁰ Being a strategic decision which may affect other projects and/or Calls, it needs to be prior coordinated and agreed by EFPIA/RDG among the companies.

<p>Implementation</p>	<p><u>In Full Project Proposal:</u></p> <ul style="list-style-type: none"> • Specification of the fraction of the non-EU EFPIA in-kind contribution being part of the total EFPIA in-kind contribution <p><u>In Selection Decision of the Full Project Proposals:</u></p> <ul style="list-style-type: none"> • The amount of the non-EU EFPIA in-kind contribution per IMI project together with the total EFPIA in-kind contribution • Provide the reason (eg description of activities) for applying for non-EU in kind as matching contribution • The cumulative amount of non-EU EFPIA in-kind contribution up to that date <p><u>In Grant Agreement:</u></p> <ul style="list-style-type: none"> • Special clause 13 a) with explicit specification of the fraction of the non-EU EFPIA in-kind contribution being part of the total EFPIA in-kind contribution (core grant agreement) • Description of the activities concerned and related estimated budget in the Description of Work (Annex I) 	<p><u>At Call launch:</u> The <u>IMI Governing Board decision</u> prior to launch should contain</p> <ul style="list-style-type: none"> • an explanation of the rationale to be accepted as a “special project” followed by description of the non-EU EFPIA in-kind contribution as part of the EFPIA in-kind contribution <p>The <u>introduction to the Call Topics Text</u> should contain</p> <ul style="list-style-type: none"> • Rationale for being a special project accepting non-EU in-kind <p><u>In Grant Agreement:</u></p> <ul style="list-style-type: none"> • Special clause 13 b) with explicit specification of the fraction of the non-EU EFPIA in-kind contribution being part of the total EFPIA in-kind contribution (Core grant agreement) • Description of the activities concerned and related estimated budget in the Description of Work (Annex I)
<p>Reporting by EFPIA companies</p>	<p>Reported as EFPIA in-kind contribution in accordance with the usual accounting and management principles and practices of the EFPIA company concerned, Total in kind and the proportion of non-EU in kind should be reported in the Financial statements (Form C) and in the summary financial report</p>	
<p>Reporting by the Executive Office</p>	<p>Regular report to the IMI Governing Board Financial reporting in the Annual Activity Report</p>	

Annex III – Participation in IMI projects of clinical sites whose contribution to the project is limited to the recruitment and inclusion of patients into the trial

The IMI projects may require that important parts of the work to be carried out by the consortia will consist of clinical trials. This may imply the involvement of a significant number of centres increasing the administrative burden of coordinators.

Normally, in accordance with the IMI legal framework, these centres should be integrated into the consortium as participant/beneficiary, as any entity contributing to IMI projects.

Nevertheless this solution does not seem to be practical or feasible where the number of sites carrying out clinical trials might make the management of the project cumbersome and/or because these centres themselves consider the responsibilities linked to full beneficiary status not as proportionate to their involvement.

Options

In cases where the contribution to the project of clinical centres is limited to the recruitment and inclusion of patients into the trial, the following options might offer acceptable alternatives:

- The clinical site is considered as a *"third party making available its resources"* to a participant (based on Article II.3.a) to d) -reimbursed- and II.13.5 -free of charge- of the IMI model grant agreement)

Implementation:

- As any third party, the clinical sites need to be described in the Description of Work (Annex I to the grant agreement).
- Costs of the clinical site are declared by the participant to whom the resources are made available in accordance with the relevant provisions of the IMI grant agreement.

The participant to whom the resources are made available

if a beneficiary, is reimbursed by the IMI JU according to the applicable funding rate;

if an EFPIA Company, claims this amount as in-kind contribution,

whether the third party contribution is reimbursed by the participant or free of charge.

- When reimbursed, the eligible costs incurred for the resources made available by a third party charged to the project shall exclude any profit for the third party.
- Third parties are required to have a *prior* agreement with the participant that defines the frame in which these resources are made available. This can be a

longstanding agreement covering a large range of areas of cooperation, but may also be specific to the project and the resources in question.

Such an agreement aims at ensuring that:

- principles of transparency and equality are respected in the selection of the third party
 - costs charged on the project reflect the usual practice of the cooperation between the third party and the concerned participant
 - No overhead may be charged by the linked participant for the amount of costs incurred by the third party.
- The clinical site is considered as a *subcontractor* (based on Article II.7 of the IMI model grant agreement)

Implementation:

- The concerned participant pays the subcontractor based on the agreed price and in turn is reimbursed by/claims to the IMI JU according to the applicable rules.
- As any subcontracting tasks, they need to be described in the Description of Work.
- Any subcontract must be awarded to the bid offering best value for money (best price-quality ratio), under conditions of transparency and equal treatment. Participants that are public bodies are reminded that the selection of subcontractors has to follow their internal rules and applicable legislation related to public procurement in order for the related costs to be eligible.
- No overhead may be charged by the linked participant for the amount of costs incurred by the subcontractor.

See Part 1 – Section 3 of the IMI Financial Guidelines summarising the boundaries conditions and financial implications.

As a general principle:

When participants or third parties cannot substantiate each of the actual costs incurred for each individual test, the participant or third party may opt to charge an average cost per patient or per test or type of test, calculated with a methodology based on its actual costs and that is auditable.