



Innovative Medicines Initiative

IMI-GB-DEC-2012-8 Annex 6

**IMI JOINT UNDERTAKING MODEL *GRANT AGREEMENT*
ANNEX VI - FORM D
TERMS OF REFERENCE FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS**

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The "Terms of Reference" should be completed by the *participants* and be agreed with the Auditor.

The "Independent Auditor Report of Factual Findings" including the procedures should be completed and provided by the Auditor.



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Introduction

The Certificate on the Financial Statements has to be submitted by the *participant* to the *IMI JU* together with the Financial Statement (Form C – Annex V to the *IMI JU grant agreement*) when required by the *IMI JU grant agreement* (Article II.4.4).

The objective of the Certificate on Financial Statements is to assist the *IMI JU* in evaluating whether the costs claimed by the *beneficiaries* and the *in kind contribution* provided by *EFPIA companies* have been reported in accordance with the *grant agreement*. It is also meant to help *participants* and their auditors defining the scope and the requirements of this exercise, as this type of engagement constitutes neither an audit nor a review made in accordance with International Standards on Auditing or on Review Engagements.

The Certificate on Financial Statements shall be issued by an independent auditor. The role of the auditor is to perform agreed-upon procedures and to provide a report of factual findings. The auditor undertakes this engagement in accordance with the terms of reference stipulated in this Annex, in accordance with the International Standard on Related Services *4400 Engagements to perform Agreed-upon Procedures regarding Financial Information*, and in compliance with the *Code of Ethics for Professional Accountants*.

The Certificate on Financial Statements is composed of the following three separate documents:

1. *A list of the terms of reference (sections 1.1 to 1.8) required by the IMI JU to be included in the engagement letter between the participant and the auditor.* The engagement letter must be dated and signed by both parties. The *IMI JU* will receive a copy of the engagement letter.
2. *The model Independent Auditor Report of Factual Findings.* The report is to be issued on the auditor's letterhead, dated, stamped and signed by the auditor. The *IMI JU* will receive the original of this report.
3. *A detailed description including the procedures to be performed by the auditor and the findings resulting from these procedures.* The description of procedures has the form of a table which has to be dated, stamped and signed by the auditor on completion of his/her work and to be part of the auditor's report. The left-hand column of the table lists procedures to be performed by the auditor. The right-hand column shows standard findings. The auditor shall adapt the standard findings to the *participant's* situation and insert any exception noted.

Note: Different procedures for *beneficiaries*¹ and *EFPIA companies* are foreseen and therefore this Annex VI contains two different tables. The auditor of a *beneficiary* shall use the table "*Procedures to be performed by the auditor for a beneficiary*". The auditor of an *EFPIA company* shall use the table "*Procedures to be performed by the auditor for an EFPIA company*".

Annex VI – Form D takes into account differences between *participants*, i.e. *beneficiaries* and *EFPIA companies* providing *in kind contribution* and therefore offers different options in the engagement letter as well as for the auditor's report, e.g. use of external auditor or public officer, different reason for engagement (e.g. certification of costs claimed by the *beneficiaries* or certification of the reported *in kind contribution*). *Participants* and auditors shall delete options which are not relevant.

¹ The "Procedures to be performed by the auditor for a *beneficiary*" also apply to *third parties* linked to a *beneficiary*.

Terms of Reference for the Independent Auditor Report of Factual Findings on costs claimed under an IMI Joint Undertaking (*IMI JU*) grant agreement

A guide on how to outline the agreement (i.e. engagement letter) between the participant and the auditor to provide a certificate on the Financial Statements in form of an independent auditor report on the financial statement prepared by the participant. When drafting the terms please select the appropriate options applicable for the participant, see options given below.

Terms of Reference

The following are the terms of reference ('ToR') on which **<name of the participant>** 'the participant' agrees to engage **< name of the audit firm>** 'the Auditor' to provide an independent auditor report of factual findings on a Financial Statement(s)² prepared by the *participant* and to report in connection with an *IMI JU grant agreement*, concerning **<title and number of the grant agreement>** (the '*grant agreement*'). Where in these ToR the '*IMI JU*' is mentioned this refers to its quality as signatory of the *grant agreement* with the *participant*. For clarification purposes, the *IMI JU* is not a party to this engagement.

1.1 Responsibilities of the Parties to the Engagement

'**The participant**' refers to the legal entity that has signed the *grant agreement* with the *IMI JU*.³

- The *participant* is responsible for preparing a Financial Statement for the Action funded by the *grant agreement* in compliance with such agreements and providing it to the Auditor, and for ensuring that this Financial Statement can be properly reconciled to the *participant's* accounting and bookkeeping system and to the underlying accounts and records. Notwithstanding the procedures to be carried out, the *participant* remains at all times responsible and liable for the accuracy of the Financial Statement.
- The *participant* is responsible for the factual statements which will enable the Auditor to carry out the procedures specified, and will provide the Auditor with a written representation letter supporting these statements, clearly dated and stating the period covered by the statements.
- The *participant* accepts that the ability of the Auditor to perform the procedures required by this engagement effectively depends upon the *participant* providing full and free access to the *participant's* staff and its accounting and other relevant records.

'**The Auditor**' refers to the Auditor who is responsible for performing the agreed-upon procedures as specified in these Terms of Reference, and for submitting an independent auditor report of factual findings to the *participant*.

The Auditor must be independent from the *participant*.

² Financial Statement in this context refers solely to Form C - Annex V by which the *participant* claims/declares costs under the *grant agreement*.

³ Where special clause 4 for the IMI Model *grant agreement* applies, this Form shall be filled in also by *third parties* linked to a *participant*. In that case, the wording "the *participant*" shall be read as "the *third party*".



[Option 1: delete if not applicable] The Auditor is qualified to carry out statutory audits of accounting documents in accordance with the Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations.

[Option 2: delete if not applicable] The Auditor is a Competent Public Officer for which the relevant national authorities have established the legal capacity to audit the *participant* and has not been involved in the preparation of the financial statements.

The procedures to be performed are specified by the *IMI JU* and the Auditor is not responsible for the suitability and appropriateness of these procedures.

1.2 Subject of the Engagement

The subject of this engagement is the **<interim or final; delete what is not applicable>** Financial Statement in connection with the *grant agreement* for the period covering **<dd Month yyyy to dd Month yyyy>**.

1.3 Reason for the Engagement

[Option 1 only for beneficiaries; paragraph to be removed for EFPIA companies] The *beneficiary* is required to submit to the *IMI JU* a certificate on a Financial Statement in the form of an independent auditor report of factual findings produced by an external auditor in support of the payment requested by the *beneficiary* under article II.4 of the *grant agreement*. The Authorising Officer of the *IMI JU* requires this Report as he/she makes the payment of costs requested by the *beneficiary* conditional on the factual findings of this Report.

[Option 2 only for EFPIA companies; paragraph to be removed for beneficiaries] The *EFPIA company* is required to submit to the *IMI JU* a certificate on a Financial Statement in the form of an independent auditor report of factual findings produced by an external auditor in support of the *in kind contribution* declared by the *EFPIA company*.

1.4 Engagement Type and Objective

This constitutes an engagement to perform specific agreed-upon procedures regarding an independent auditor report of factual findings on costs claimed/declared **[please select]** under the *grant agreement*.

As this engagement is not an assurance engagement the Auditor does not provide an audit opinion and expresses no assurance.

[Option 1 only for beneficiaries; paragraph to be removed for EFPIA companies] The *IMI JU* derives its assurance by drawing its own conclusions from the factual findings reported by the Auditor on the Financial Statement and the payment request of the *beneficiary* relating thereto.

[Option 2 only for EFPIA companies; paragraph to be removed for beneficiaries] The *IMI JU* derives its assurance by drawing its own conclusions from the factual findings reported by the Auditor on the Financial Statement and the *in kind contribution* of the *EFPIA company* relating thereto.

The Auditor shall include in its Report that no conflict of interest exists between it and the *participant* in establishing this Report, as well as the fee (excluding VAT) paid to the Auditor for providing the Report.



1.5 Scope of Work

1.5.1 The Auditor shall undertake this engagement in accordance with these ToR and:

- in accordance with the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as promulgated by the IFAC;
- in compliance with the *Code of Ethics for Professional Accountants* issued by the IFAC. Although ISRS 4400 provides that independence is not a requirement for agreed-upon procedures engagements, the *IMI JU* requires that the Auditor also complies with the independence requirements of the *Code of Ethics for Professional Accountants*.

1.5.2 Planning, procedures, documentation and evidence

The Auditor should plan the work so that the procedures can be effectively performed. For this purpose he/she performs the procedures specified in 1.9 of these Terms of Reference ('Scope of Work – Compulsory Report Format and Procedures to be performed') and uses the evidence obtained from these procedures as the basis for the Report of factual findings.

1.6 Reporting

The Report of factual findings, an example of which is attached to this terms of reference, should describe the purpose and the agreed-upon procedures of the engagement in sufficient detail in order to enable the *participant* and the *IMI JU* to understand the nature and extent of the procedures performed by the Auditor.

Use of the reporting format (*Independent Auditor Report of Factual Findings*) that is described in this Annex VI is compulsory.

The Report should be written in the language indicated in Article 4 of the *grant agreement*. Subject to Article II.21 of the *grant agreement*, the *IMI JU*, the European Commission including OLAF, and the Court of Auditors have the right to audit any work carried out by *beneficiaries* under the *project* for which costs are claimed from the *IMI JU*, including the work related to this engagement. In addition, the *IMI JU* has the right to audit any work carried out by *EFPIA companies* under the *project* for which *in kind contribution* is declared to *IMI JU*, including the work related to this engagement.

1.7 Timing

The Report should be provided by [DATE].

1.8 Other Terms

[The participant and the Auditor can use this section to agree other specific terms such as Auditor's fees, out of pocket expenses, liability, applicable law, etc.]

[legal name of the audit firm]

[legal name of the participant]

[name & function of authorised representative]

[name & function of authorised representative]

<dd Month yyyy>

<dd Month yyyy>



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<Signature of the Auditor>

<Signature of the participant>

1.9 Scope of Work – Compulsory Report Format and Procedures to be performed

The Independent Auditor Report of Factual Findings and the procedures to be performed form part of these terms of reference.

[Legal name of the participant]
[Name and function]

[Legal name of the audit firm]
[Name and function of an authorised representative]

Date:
Signature:

Date:
Signature of the Auditor:



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Independent Auditor Report of Factual Findings on costs claimed/declared under an *IMI JU grant agreement*

To be printed on letterhead paper of the Auditor

Independent Auditor Report of Factual Findings on costs claimed/declared under an *IMI JU grant agreement*

<Name of contact person(s)>

< Position>

< *Participant's name*>

<Address>

<dd Month yyyy>

In accordance with our contract dated <dd Month yyyy> with <name of the participant> “the participant” and the terms of reference attached thereto (appended to this Report), we provide our Independent Auditor Report of Factual Findings (“the Report”), as specified below.

Objective

We [*legal name of the audit firm*], established in [*full address/city/state/province/country*] represented for signature of this Report by [*name and function of an authorised representative*] have performed agreed-upon procedures regarding the cost declared in the Financial Statement(s)⁴ of [*name of participant*] hereinafter referred to as the *participant*, to which this Report is attached, and which is to be presented to the *IMI JU* under *grant agreement* [*IMI JU grant agreement reference: title, acronym, number*] for the following period(s) [*insert period(s) covered by the Financial Statement(s)*] and for the following amount [*insert amount in EUR*]. This engagement involved performing certain specified procedures, the results of which the *IMI JU* uses to draw conclusions as to the eligibility of the costs claimed.

Scope of Work

Our engagement was carried out in accordance with:

- the terms of reference appended to this Report;
- International Standard on Related Services (‘ISRS’) 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as promulgated by the International Federation of Accountants (‘IFAC’); and
- the *Code of Ethics for Professional Accountants* issued by the IFAC. Although ISRS 4400 provides that independence is not a requirement for agreed-upon procedures engagements, the *IMI JU*

⁴ Financial Statement in this context refers solely to Annex V – Form C by which the *participant* claims/declares costs under the *grant agreement*.



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requires that the Auditor also complies with the independence requirements of the *Code of Ethics for Professional Accountants*.

As requested, we have only performed the procedures set out in the terms of reference for this engagement and we have reported our factual findings on those procedures in the table appended to this Report.

The scope of these agreed upon procedures has been determined solely by the *IMI JU* and the procedures were performed solely to assist the *IMI JU* in evaluating whether the costs claimed/declared by the *participant* in the accompanying Financial Statement has been claimed/declared in accordance with the *grant agreement*. The Auditor is not responsible for the suitability and appropriateness of these procedures.

Because the procedures performed by us did not constitute either an audit or a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not express any assurance on the Financial Statements.

Had we performed additional procedures or had we performed an audit or review of the Financial Statements of the *participant* in accordance with International Standards on Auditing, other matters might have come to our attention that would have been reported to you.

Sources of Information

The Report sets out information provided to us by the management of the *participant* in response to specific questions or as obtained and extracted from the *participant's* information and accounting systems.

Factual Findings

The above mentioned Financial Statement(s) per Activity was (were) examined and all procedures specified in the appended table for our engagement were carried out. On the basis of the results of these procedures, we found:

All documentation and accounting information to enable us to carry out these procedures has been provided to us by the *participant*. Except as indicated below, no exceptions were noted.

Exceptions

In some cases, the Auditor was not able to successfully complete the procedures specified. These exceptions are as follows:

Exceptions such as inability to reconcile key information, unavailability of data which prevented the Auditor from carrying out the procedures, etc. should be listed here. The *IMI JU* will use this information to decide the amounts which will be reimbursed.

Use of this Report

This Report is solely for the purpose set forth in the above objective.



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This Report is prepared solely for the confidential use of the *participant* and the *IMI JU* and solely for the purpose of submission to the *IMI JU* in connection with the requirements as set out in Article II.4.4 of the *grant agreement*. This Report may not be relied upon by the *participant* or by the *IMI JU* for any other purpose, nor may it be distributed to any other parties.

The *IMI JU* may only disclose this Report to others who have regulatory rights of access to it, in particular the European Commission, including the European Anti-Fraud Office, and the European Court of Auditors.

This Report relates only to the Financial Statement(s) specified above and does not extend to any other financial statements of the *participant*.

No conflict of interest exists⁵ between the Auditor and the *participant* in establishing this Report. The fee paid to the Auditor for providing the Report was € _____ (excluding VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

[Legal name of the audit firm]

[Name and function of an authorised representative]

<dd Month yyyy>

<Signature of the Auditor>

⁵ A conflict of interest arises when the auditor's objectivity to establish the certificate is compromised in fact or in appearance when the auditor for instance:

- was involved in the preparation of the Financial Statements (Forms C);
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the *participant*;
- is a director, trustee or partner of the *participant*;
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Procedures to be performed by the auditor for a *beneficiary*

Procedures performed by the auditor

The Auditor designs and carries out his work in accordance with the objective and scope of this engagement and the procedures to be performed as specified below. When performing these procedures the Auditor may apply techniques such as inquiry and analysis, (re)computation, comparison, other clerical accuracy checks, observation, inspection of records and documents, inspection of assets and obtaining confirmations or any others deemed necessary in carrying out these procedures.

The IMI JU reserves the right to issue guidance together with example definitions and findings to guide the Auditor in the nature and presentation of the facts to be ascertained. The IMI JU reserves the right to vary the procedures by written notification to the *beneficiary*. The procedures to be performed are listed as follows:

Procedures	Standard factual finding and basis for exception reporting
Personnel Costs¹.	
1. a) Recalculate hourly personnel and overhead rates for personnel (full coverage if less than 20 employees, otherwise a sample of minimum 20, or 20% of employees, whichever is the greater.	The auditor sampled _____ employees out of the total of _____ employees. a) For each employee in the sample of _____ [indicate number], the Auditor obtained the personnel costs (salary and employer's costs) from the payroll system together with the productive hours from the time records of each employee. For each employee selected, the Auditor recomputed the hourly rate by dividing the actual personnel costs by the actual productive hours, which was then compared to the hourly rate charged by the <i>beneficiary</i> .

¹Procedure n°1.a) does not apply if average personnel costs are used, i.e. if there is a certified methodology approved by the European Commission (see procedure 4). The auditor is expected to check the compliance with the methodology. In this case, the auditor is therefore requested to check only the part related to productive hours (1.b) in this procedure.

Procedures	Standard factual finding and basis for exception reporting
	No exceptions were noted.
<p>b) Indicate the number of productive hours used and hourly rates. Where sampling is used, selection should be random with a view to producing a representative sample. 'Productive hours' represent the (average) number of hours made available by the employee in a year after the deduction of holiday, sick leave and other entitlements. The auditor obtained the calculation of the productive hours after inspecting all necessary records, national legislation, labour agreements, contracts, and any other relevant documentation. The calculation should be based on the period(s) corresponding to the Financial Statement(s) or on the last closed financial year (whichever is used by the beneficiary).</p>	<p>b) The average number of productive hours for the employees selected was _____ [indicate number]. The productive hours calculation corresponds to the usual accounting practice of the beneficiary. If the productive hours or costs of personnel cannot be identified, they should be listed (together with the amounts) as exceptions in the main report. If the productive hours calculation does not correspond to the usual accounting practice of the beneficiary, this should be reported as an exception in the main report.</p>
<p>2. For the same selection examine and describe time recording of employees (paper/ computer, daily/weekly/monthly, signed, authorised).</p>	<p>Employees record their time on a [daily/ weekly/ monthly] basis using a [paper/computer]-based system. The time-records selected were authorised by the project manager or other superior. If no time records are available which fit the above description, this should be listed as an exception in the main report.</p>

Procedures	Standard factual finding and basis for exception reporting
<p>3. Employment status and employment conditions of personnel. The Auditor should obtain the employment contracts of the employees selected and compare with the standard employment contract used by the <i>beneficiary</i>. Differences which are not foreseen by the <i>grant agreement</i> should be noted as exceptions.</p>	<p>For the employees selected, the Auditor inspected their employment contracts and found that they were:</p> <ul style="list-style-type: none"> - directly hired by the <i>beneficiary</i> in accordance with its national legislation, - under the sole technical supervision and responsibility of the latter, and - remunerated in accordance with the normal practices of the <i>beneficiary</i>. <p>Personnel who do not meet all three conditions should be listed (together with the amounts) as exceptions in the main report.</p>
<p>4. Use of average personnel costs^{2 3}</p> <p>a) With an approved certified methodology including average personnel costs:</p>	<p>a) The Auditor found that the personnel costs charged to the financial statement:</p> <ul style="list-style-type: none"> - are calculated using average costs in accordance with the methodology as specified in the Report of findings on the methodology dated _____ in accordance with article II.13.2; - have been calculated using amounts derived from the relevant period which can be reconciled to the accounting records of the relevant period. <p>Where categories are used, the Auditor verified that the researcher (or research-related person) had been correctly classified.</p> <p>The Auditor obtained confirmation from the <i>beneficiary</i> that the rates used were not budgeted or estimated amounts.</p> <p>If amounts cannot be reconciled, or if estimates or budgeted amounts were used, this</p>

² Procedure n°4 does not apply if the *beneficiary* does not use averages for the calculation of personnel costs

³ Apply 4a, 4b or 4c according to the existence or not of a certified methodology approved by the European Commission within the Seventh Framework Programme (CoMAv, or CoM if it concerns average personnel costs)

Procedures	Standard factual finding and basis for exception reporting
<p>b) Without an approved certified methodology (not applicable to SME owners and natural persons not receiving a salary):</p> <ul style="list-style-type: none"> • The auditor reviewed all relevant manuals and/or internal guidance describing the methodology used to calculate average personnel costs. • The auditor obtained a list of all average personnel rates calculated by the beneficiary in accordance with the methodology used. • The auditor verified that the calculation of the average personnel costs excludes ineligible items as defined in article II.13.6, or any costs claimed under other cost categories. • The auditor obtained a list of all relevant employees (working on EU-funded projects + not working on EU-funded projects) based on which the average personnel rate(s) are calculated. • The auditor reviewed the allocation of employees to the relevant group and verified the correctness of the Full Time Equivalent (FTE). • The auditor performed a numerical reconciliation 	<p>should be reported as an exception in the main report.</p> <p>b) The auditor found:</p> <ul style="list-style-type: none"> - no discrepancies between the method described in the relevant documents and the method used by the <i>beneficiary</i>; - the methodology used to calculate the average personnel hourly rate(s) represent(s) the usual cost accounting practice of the organisation; - no differences arose from the numerical reconciliation. <p>The Auditor confirms that the rates used for the calculation of the average personnel costs were not based on budgeted or estimated amounts.</p> <p>If amounts cannot be reconciled, or if estimates or budgeted amounts were used, this should be reported as an exception in the main report.</p> <p>If the usual accounting practice differs from the one described, this should be reported as an exception in the main report.</p>

Procedures	Standard factual finding and basis for exception reporting
<p>between the total amount of personnel costs taken into consideration for the calculation of the average personnel rate and the total amount of personnel costs recorded in the statutory accounts.</p> <ul style="list-style-type: none"> The auditor verified on a sample basis that the appropriate average hourly rate was used for the personnel costs claimed on the audited project. <p>c) Without an approved certified methodology – applicable only for SME owners and natural persons not receiving a salary:</p> <ul style="list-style-type: none"> The auditor reviewed payroll and accounting records, contracts and other relevant legal documents in order to verify that the SME owners and the natural persons concerned do not receive any salary. The auditor obtained documents (such as employment records, CVs, diplomas and other relevant documents) proving professional experience of the persons concerned and supporting determination of appropriate research category in line with 'People' Work Programme of the Seventh Framework Programme. The auditor verified that the annual living allowance corresponds to the reference year of the publication of the call under which the project was selected for funding and that the beneficiary applied the appropriate country 	<p>c) SME owners and natural persons charging personnel costs based on a flat rate, do not receive salary.</p> <p>If they receive any salary, it should be listed as an exception in the main report.</p> <ul style="list-style-type: none"> Time spent on projects was duly recorded by the persons whose personal work costs are charged on the basis of a flat rate. These time-records have been verified by a superior or another person involved in the project. In the absence of any superior or other person working closely with such persons, the Auditor confirms that documentation is available to ascertain the reliability of the time records. <p>If no time records are available, this should be listed as an exception in the main report.</p> <ul style="list-style-type: none"> The hourly rates applicable to all SME owners and natural persons who do not receive a salary are correctly calculated. The total number of hours claimed for the IMI project in a year is in line with their time-sheets but is not higher than the standard number of productive hours per SME owner

Procedures	Standard factual finding and basis for exception reporting
<p>coefficient correction as published in the above mentioned 'People' Work Programme of the year of publication of the call.</p> <ul style="list-style-type: none"> • The auditor recomputed the hourly rate by dividing the applicable living allowance corresponding to the appropriate research category by the standard number of productive hours (1575) and by multiplying it by the appropriate country correction coefficient. • The auditor reviewed the time-sheets completed by the persons whose personal work costs are claimed on a flat rate basis. 	<p>or natural person (1575).</p> <p>If the calculation is not correct, this should be listed as an exception in the main report.</p>



Subcontracting	
<p>5. Obtain a written description from the <i>beneficiary</i> regarding <i>third party</i> resources used and compare with Annex 1 to the <i>grant agreement</i>.</p>	<p>The Auditor compared the description of the <i>third party</i> resources provided by the <i>beneficiary</i> to the specification in Annex 1 to the <i>grant agreement</i>, and found them to be the same.</p> <p>If the descriptions do not clearly match, this should be reported as an exception in the main report.</p>
<p>6. Inspect documents and obtain confirmations that subcontracts are awarded according to a procedure including an analysis of best value for money (best price-quality ratio), transparency and equal treatment. Full coverage if less than 20 items, otherwise a sample of minimum 20, or 20% of the items, whichever is the greater.</p>	<p>The Auditor obtained tendering documents for each subcontract entered into and found that the tendering process was followed and that a written analysis of value-for-money had been prepared by the <i>beneficiary</i> in support of the final choice of subcontractor, or that the contract had been awarded as part of an existing framework contract entered into prior to the beginning of the <i>project</i>.</p> <p>If the Auditor is not provided with evidence of either of the above situations, the amount of the subcontract should be listed as an exception in the main report.</p>
Other Direct Costs	
<p>7. Allocation of equipment subject to depreciation is correctly identified and allocated to the <i>project</i>. Full coverage if less than 20 items, otherwise a sample of minimum 20, or 20% of the items, whichever is the greater.</p>	<p>The Auditor traced the equipment charged to the <i>project</i> to the accounting records and the underlying invoices. The <i>beneficiary</i> has documented the link with the <i>project</i> on the invoice and purchase documentation, and, where relevant, the <i>project</i> accounting. The asset value was agreed to the invoice and no VAT or other identifiable indirect taxes were charged. The depreciation method used to charge the equipment to the <i>project</i> was compared to the <i>beneficiary's</i> normal accounting policy and found to be the same.</p> <p>If assets have been charged which do not comply with the above, they should be listed (together with the amounts) as exceptions in the main report.</p>



<p>8. Travel costs correctly identified and allocated to the <i>project</i> (and in line with <i>beneficiary's</i> normal policy for non-IMI JU work regarding first-class travel, etc.) Full coverage if less than 20 items, otherwise a sample of minimum 20, or 20% of the items, whichever is the greater. The <i>beneficiary</i> should provide written evidence of its normal policy for travel costs (e.g. use of first class tickets) to enable the Auditor to compare the travel charged with this policy.</p>	<p>The Auditor inspected the sample and found that the <i>beneficiary</i> had allocated travel costs to the <i>project</i> by marking of invoices and purchase orders with the <i>project</i> reference, resulting in traceable allocation in the <i>project</i> accounts. The costs charged were compared to the invoices and found to be the same. No VAT or other identifiable indirect taxes were charged. The use of first class travel was in line with the written policy provided by the <i>beneficiary</i>. Costs which are not allocated to <i>project</i> accounts and do not have a clear attribution (normally by writing the <i>project</i> number on the original invoice) should be listed (together with the amounts) as exceptions in the main report.</p>
<p>9. Consumables correctly identified and allocated to the <i>project</i>. Full coverage if less than 20 items, otherwise a sample of minimum 20, or 20% of the items, whichever is the greater.</p>	<p>The Auditor inspected the sample and found that the <i>beneficiary</i> had allocated consumable costs to the <i>project</i> by marking of invoices and purchase orders with the project reference, resulting in traceable allocation in the <i>project</i> accounts. The costs charged were compared to the invoices and found to be the same. No VAT or other identifiable indirect taxes were charged. Costs which are not allocated to <i>project</i> accounts and do not have a clear attribution (normally by writing the <i>project</i> number on the original invoice) should be listed (together with the amounts) as exceptions in the main report.</p>

Indirect costs ^{4,5}	
<p>10. Obtain and review a detailed breakdown of indirect costs (reconciled to the accounting records) and confirm that the following costs are not present:</p> <ul style="list-style-type: none"> a) identifiable indirect taxes including value added tax, b) duties, c) interest owed, d) provisions for possible future losses or charges, e) exchange losses, cost related to return on capital, f) costs declared or incurred, or reimbursed in respect of another Union or Euratom project, g) debt and debt service charges, excessive or reckless expenditure. <p>The above does not apply to <i>beneficiaries</i> using a flat rate to claim indirect costs in accordance with Annex II of the <i>IMI JU grant agreement</i> being reviewed. In such case the procedure to apply is:</p> <ul style="list-style-type: none"> - The auditor confirmed that the flat rate applied on the 	<p>The Auditor obtained the total overhead amount which was allocated and reconciled this to the accounting records for the period in question.</p> <p>The Auditor recalculated the ratio of indirect costs [as a percentage of personnel costs/ as a fixed personnel hourly rate / as another cost driver specified by the <i>beneficiary</i>] and agreed it to the rate used in the Financial Statement(s).</p> <p>The Auditor obtained a detailed breakdown from the accounting system of the indirect costs which have been charged to the <i>project</i>, and reconciled the individual amounts to the general ledger of the <i>beneficiary</i>.</p> <p>The Auditor found that costs for the non-research activities of the <i>beneficiary</i>, such as manufacturing, education, marketing of products or services, etc., had not been included in the calculation.</p> <p>For each element of the breakdown, the Auditor obtained the <i>beneficiary's</i> confirmation that it contained none of the ineligible costs specified (typical examples are leasing costs, loan charges, provisions for doubtful debt (but not normal accruals), local business and property taxes, customs duties, exchange losses from billing in a foreign currency).</p> <p>Amounts which do not meet the above criteria or where the Auditor is not provided with sufficient information in order to inspect and compare the types of cost should be listed (together with the amounts) as exceptions in the main report.</p> <p>Only for <i>beneficiaries</i> using a flat rate to claim indirect costs:</p> <p>The auditor found:</p> <ul style="list-style-type: none"> - that the flat rate has been charged in accordance with Annex II of the <i>IMI JU grant agreement</i> and computed on direct eligible costs excluding costs for sub-contracting and the costs of resources made available by third parties which are not used on the

⁴ The auditor does not need to check indirect costs if they are reported as a flat rate of direct eligible costs.

⁵ Procedure n°12 applies only to *beneficiaries* using the simplified method (as stipulated in Article II.14.2.a) of the *grant agreement*).



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Financial Statement(s) is consistent with the one provided in Annex II of the *IMI JU grant agreement*.

- The auditor recalculated the indirect costs claimed on the basis of the flat rate for arithmetical accuracy.

premises of the *beneficiary*;
- that no differences arose from the numerical reconciliation.

<p>11. Assess use of a simplified method of calculation of overheads at the level of the legal entity. The <i>beneficiary</i> may use a simplified method of calculation (either due to the lack of analytical accounting or legal requirement to use a form of cash-based accounting). This does not permit the use of a generalised estimate, or the use of a 'standard' rate that is not derived from the accounting records of the period in question. Thus the rate (but not the methodology) should be updated for each accounting period.</p>	<p>The <i>beneficiary's</i> accounting system does not permit indirect costs to be separately identified for the individual departments.</p> <p>[and/ or]</p> <p>The <i>beneficiary's</i> accounting system is cash-based and year-end adjustments are made using accounting estimates in order to charge certain accrued costs.</p> <p>The Auditor obtained the breakdown of overhead costs and the adjusting entries together with the source of the relevant accounting entries.</p> <p>The <i>beneficiary</i> provided the Auditor with underlying calculations showing the basis for additional accounting entries. The Auditor agreed these calculations to the relevant sources of management information.</p> <p>Any elements of a simplified calculation which represent percentage estimates and which cannot be compared to underlying data should be listed (together with the amounts) as exceptions in the main report.</p>
<p>Other^{6,7}</p>	
<p>12. Inspect and compare exchange rates into Euros.</p>	<p>The Auditor compared the exchange rates used for conversion with the applicable official exchange rates established by the European Central Bank and the <i>beneficiary</i> used</p> <p>[choose one / delete option which is not applicable]</p> <p>[Option 1] the conversion rate of the date where the actual costs were incurred</p> <p>[Option 2] the rate applicable on the first day of the month following the end of reporting period</p> <p>Where rates cannot be agreed, an exception should be noted, (together with the amount) in the main report.</p>

⁶ Procedure n°13 does not apply to *beneficiaries* with accounts in EUR and costs incurred in other currencies.

⁷ Procedure n°15 applies only to the *Managing Entity of the IMI JU funding*.



<p>13. Identification of receipts (<i>EFPIA</i> and other receipts). The <i>beneficiary</i> is obliged to declare in its claim any receipts (<i>EFPIA</i> and other receipts) related to the <i>project</i> (income from events, rebates from suppliers, etc.)</p>	<p>The Auditor examined the relevant <i>project</i> accounts and obtained representations from the <i>beneficiary</i> that the amounts listed represent a complete record of the sources of income connected with the <i>project</i>. The amount included in the claim regarding receipts is the same as the amount recorded in the <i>project</i> accounting. Any discrepancies in the receipts noted in the accounts and those reported by the <i>beneficiary</i> should be noted (together with the amount) as exceptions in the main report.</p>
<p>14. Identification of interest yielded on pre-financing. The <i>beneficiary</i>, when it is the <i>managing entity of the IMI JU funding</i>, is obliged to declare interest yielded on pre-financing.</p>	<p>The Auditor compared the relevant <i>project</i> accounts with the interest shown in the bank statements and found them to be the same. Any discrepancies in the interest noted in the accounts and those reported by the <i>beneficiary</i> should be noted (together with the amount) as exceptions in the main report.</p>

[Legal name of the audit firm]

[Name and function of an authorised representative of the audit firm]

<dd Month yyyy>

<Signature of the Auditor>



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Procedures to be performed by the auditor for an *EFPIA company*

Procedures performed by the auditor for an *EFPIA company*

The Auditor designs and carries out his work in accordance with the objective and scope of this engagement and the procedures to be performed as specified below. When performing these procedures the Auditor may apply techniques such as inquiry and analysis, (re)computation, comparison, other clerical accuracy checks, observation, inspection of records and documents, inspection of assets and obtaining confirmations or any others deemed necessary in carrying out these procedures.

The *IMI JU* reserves the right to issue guidance together with example definitions and findings to guide the Auditor in the nature and presentation of the facts to be ascertained. The *IMI JU* reserves the right to vary the procedures by written notification to the *EFPIA company*. The procedures to be performed are listed as follows:

Important remarks:

- Depending on the "Certified methodology on *in kind contribution*" of the *EFPIA company*, procedures n ° 1a, 7; 8; 9 and 10 may not be applicable.
- Procedures 1 to 14 shall also be applied for *in kind contribution* of research activities conducted outside a Member State or an associated country, in accordance with special clause 13 a) or b), if one of this special clauses applies.

Procedures	Standard factual finding and basis for exception reporting
Personnel Costs¹.	
<p>1.</p> <p>a) Recalculate hourly personnel and overhead rates for personnel (full coverage if less than 20 employees, otherwise a sample of minimum 20, or 20% of employees, whichever is the greater).</p> <p>b) Indicate the number of productive hours used and hourly rates. Where sampling is used, selection should be random with a view to producing a representative sample. 'Productive hours' represent the (average) number of hours made available by the employee in a year after the deduction of holiday, sick leave and other entitlements. The auditor obtained the calculation of the productive hours after inspecting all necessary records, national legislation, labour agreements, contracts, and any</p>	<p>The auditor sampled _____ employees out of the total of _____ employees.</p> <p>a) For each employee in the sample of _____ [indicate number], the Auditor obtained the personnel costs (salary and employer's costs) from the payroll system together with the productive hours from the time records of each employee. For each employee selected, the Auditor recomputed the hourly rate by dividing the actual personnel costs by the actual productive hours, which was then compared to the hourly rate declared by the <i>EFPIA company</i>. No exceptions were noted.</p> <p>b) The average number of productive hours for the employees selected was _____ [indicate number]. The productive hours calculation corresponds to the usual accounting practice of the <i>EFPIA company</i>. If the productive hours or costs of personnel cannot be identified, they should be listed (together with the amounts) as exceptions in the main report. If the productive hours calculation does not correspond to the usual accounting practice of the <i>EFPIA company</i>, this should be reported as an exception in the main report.</p>

¹Procedure n°1.a) does not apply if average personnel costs are used, i.e. if there is "certified methodology on *in kind contribution*" or a certified methodology approved by the European Commission (see Procedure n°4). The auditor is expected to check the compliance with the methodology. In this case, the auditor is therefore requested to check only the part related to productive hours (1.b) in this procedure. For those *EFPIA companies* having submitted a "certified methodology on *in kind contribution*", depending on this methodology procedure n°1 b) should refer to the equivalent of "productive hours" used by the company.



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Procedures	Standard factual finding and basis for exception reporting
<p>other relevant documentation. The calculation should be based on the period(s) corresponding to the Financial Statement(s) or on the last closed financial year (whichever is used by the <i>EFPIA company</i>).</p>	

<p>2. For the same selection examine and describe time recording of employees (paper/ computer, daily/weekly/monthly, signed, authorised).</p>	<p>Employees record their time on a [daily/ weekly/ monthly] basis using a [paper/computer]-based system. The time-records selected were authorised by the project manager or other superior.</p> <p>If no time records are available which fit the above description, this should be listed as an exception in the main report.</p>
<p>3. Employment status and employment conditions of personnel. The Auditor should obtain the employment contracts of the employees selected and compare with the standard employment contract used by the <i>EFPIA company</i>. Differences which are not foreseen by the <i>grant agreement</i> should be noted as exceptions.</p>	<p>For the employees selected, the Auditor inspected their employment contracts and found that they were:</p> <ul style="list-style-type: none"> - directly hired by the <i>EFPIA company</i> in accordance with its national legislation, - under the sole technical supervision and responsibility of the latter, and - remunerated in accordance with the normal practices of the <i>EFPIA company</i>. <p>Personnel who do not meet all three conditions should be listed (together with the amounts) as exceptions in the main report.</p>
<p>4. Use of average personnel costs^{2 3}</p> <p>a) With a certified methodology on in-kind contribution or an approved certified methodology including average personnel costs:</p>	<p>a) The Auditor found that the personnel costs declared in the financial statement</p> <ul style="list-style-type: none"> - are either calculated using average costs in accordance with the "certified methodology on <i>in kind contribution</i>"; - or are calculated using average costs in accordance with the methodology as specified in the Report of findings on the methodology dated _____ in accordance with Article II.13.2 - have been calculated using amounts derived from the relevant period which can be reconciled to the accounting records of the relevant period. <p>Where categories are used, the Auditor verified that the researcher (or research-related person) had been correctly classified.</p>

² Procedure n°4 does not apply if the *EFPIA company* does not use averages for the calculation of personnel costs.

³ Apply 4a or 4b according to the existence or not of a certified methodology on *in-kind contribution* or a certified methodology approved by the European Commission within the Seventh Framework Programme (CoMAv, or CoM if it concerns average personnel costs)

<p>b) Without a certified methodology on in-kind contribution or an approved certified methodology:</p> <ul style="list-style-type: none"> • The auditor reviewed all relevant manuals/processes and/or internal guidance describing the methodology used to calculate average personnel costs. • The auditor obtained a list of all average personnel rates calculated by the <i>EFPIA company</i> in accordance with the methodology used. • The auditor verified that the calculation of the average personnel costs excludes ineligible items as defined in article II.13.6, or any costs claimed under other cost categories. • The auditor obtained a list of all relevant employees (working on EU funded projects + not working on EU funded projects) based on which the average personnel rate(s) are calculated. • The auditor reviewed the allocation of employees to the potential relevant group and verified the correctness of the Full Time Equivalent (FTE). • The auditor performed a numerical reconciliation between the total amount of personnel costs taken into consideration for the calculation of the average personnel rate and the total amount of personnel costs 	<p>If amounts cannot be reconciled, or if estimates or budgeted amounts were used, this should be reported as an exception in the main report.</p> <p>b) The auditor found:</p> <ul style="list-style-type: none"> - no discrepancies between the method described in the relevant documents and the method used by the <i>EFPIA company</i>; - the methodology used to calculate the average personnel hourly rate(s) represent(s) the usual cost accounting practice of the organisation; - no differences arose from the numerical reconciliation. <p>The auditor confirms that the rates used for the calculation of the average personnel costs were not based on budgeted or estimated amounts.</p> <p>If amounts cannot be reconciled, or if estimates or budgeted amounts were used, this should be reported as an exception in the main report.</p> <p>If the usual accounting practice differs from the one described, this should be reported as an exception in the main report.</p>
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recorded in the statutory accounts.

- The auditor verified on a sample basis that the appropriate average hourly rate is used for the personnel costs claimed on the audited project.



Subcontracting	
5. Obtain a written description from the <i>EFPIA company</i> regarding <i>third party</i> resources used and compare with Annex 1 to the <i>grant agreement</i> .	The Auditor compared the description of the <i>third party</i> resources provided by the <i>EFPIA company</i> to the specification in Annex 1 to the <i>grant agreement</i> , and found them to be the same. If the descriptions do not clearly match, this should be reported as an exception in the main report.
6. Inspect documents and obtain confirmations that subcontracts are awarded according to a procedure including an analysis of best value for money (best price-quality ratio), transparency and equal treatment. Full coverage if less than 20 items, otherwise a sample of minimum 20, or 20% of the items, whichever is the greater.	The Auditor should ensure that the <i>EFPIA company</i> follows its internal procedures regarding each subcontract entered into including that an analysis of value-for-money had been prepared by the <i>EFPIA company</i> in support of the final choice of subcontractor, or that the contract had been awarded as part of an existing framework contract entered into prior to the beginning of the <i>project</i> . If the Auditor is not provided with evidence of either of the above situations, the amount of the subcontract should be listed as an exception in the main report.
Other Direct Costs⁴	

⁴ The auditor must determine whether procedures 7, 8 and 9 are applicable in accordance with the "certified methodology on *in kind contribution*".



<p>7. Allocation of equipment subject to depreciation is correctly identified and allocated to the <i>project</i>. Full coverage if less than 20 items, otherwise a sample of minimum 20, or 20% of the items, whichever is the greater.</p>	<p>The Auditor traced the equipment charged to the <i>project</i> to the accounting records and the underlying invoices. The <i>EFPIA company</i> has documented the link with the <i>project</i> on the invoice and purchase documentation, and, where relevant, the <i>project</i> accounting. The asset value was agreed to the invoice and no VAT or other identifiable indirect taxes were charged. The depreciation method used to charge the equipment to the <i>project</i> was compared to the <i>EFPIA company's</i> normal accounting policy and found to be the same. If assets have been charged which do not comply with the above, they should be listed (together with the amounts) as exceptions in the main report.</p>
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<p>8. Travel costs correctly identified and allocated to the <i>project</i> (and in line with <i>EFPIA company's</i> normal policy for non-IMI JU work regarding first-class travel, etc.)</p> <p>Full coverage if less than 20 items, otherwise a sample of minimum 20, or 20% of the items, whichever is the greater.</p> <p>The <i>EFPIA company</i> should provide written evidence of its normal policy for travel costs (e.g. use of first class tickets) to enable the Auditor to compare the travel charged with this policy.</p>	<p>The Auditor inspected the sample and found that the <i>EFPIA company</i> had allocated travel costs to the <i>project</i> by marking of invoices and purchase orders with the <i>project</i> reference, resulting in traceable allocation in the <i>project</i> accounts.</p> <p>The costs charged were compared to the invoices and found to be the same. No VAT or other identifiable indirect taxes were charged.</p> <p>The use of first class travel was in line with the written policy provided by the <i>EFPIA company</i>.</p> <p>Costs which are not allocated to <i>project</i> accounts and do not have a clear attribution (normally by writing the <i>project</i> number on the original invoice) should be listed (together with the amounts) as exceptions in the main report.</p>
<p>9. Consumables correctly identified and allocated to the <i>project</i>.</p> <p>Full coverage if less than 20 items, otherwise a sample of minimum 20, or 20% of the items, whichever is the greater.</p>	<p>The Auditor inspected the sample and found that the <i>EFPIA company</i> had allocated consumable costs to the <i>project</i> by marking of invoices and purchase orders with the <i>project</i> reference, resulting in traceable allocation in the <i>project</i> accounts.</p> <p>The costs charged were compared to the invoices and found to be the same. No VAT or other identifiable indirect taxes were charged.</p> <p>Costs which are not allocated to <i>project</i> accounts and do not have a clear attribution (normally by writing the <i>project</i> number on the original invoice) should be listed (together with the amounts) as exceptions in the main report.</p>

Indirect costs^{5,6,7}	
<p>10. Obtain and review a detailed breakdown of indirect costs (reconciled to the accounting records) and confirm that the following costs are not present:</p> <ul style="list-style-type: none"> a) identifiable indirect taxes including value added tax, b) duties, c) interest owed, d) provisions for possible future losses or charges, e) exchange losses, cost related to return on capital, f) costs declared or incurred, or reimbursed in respect of another Union or Euratom project, g) debt and debt service charges, excessive or reckless expenditure. <p>The above does not apply to <i>EFPIA companies</i> using a flat</p>	<p>The Auditor obtained the total overhead amount which was allocated and reconciled this to the accounting records for the period in question.</p> <p>The Auditor recalculated the ratio of indirect costs [as a percentage of personnel costs/ as a fixed personnel hourly rate / as another cost driver specified by the <i>EFPIA company</i>] and agreed it to the rate used in the Financial Statement(s).</p> <p>The Auditor obtained a detailed breakdown from the accounting system of the indirect costs which have been charged to the contract, and reconciled the individual amounts to the general ledger of the <i>EFPIA company</i>.</p> <p>The Auditor found that costs for the non-research activities of the <i>EFPIA company</i>, such as manufacturing, education, marketing of products or services, etc., had not been included in the calculation.</p> <p>For each element of the breakdown, the Auditor obtained the <i>EFPIA company's</i> confirmation that it contained none of the ineligible costs specified (typical examples are leasing costs, loan charges, provisions for doubtful debt (but not normal accruals), local business and property taxes, customs duties, exchange losses from billing in a foreign currency).</p> <p>Amounts which do not meet the above criteria or where the Auditor is not provided with sufficient information in order to inspect and compare the types of cost should be listed (together with the amounts) as exceptions in the main report.</p> <p>Only for EFPIA companies using a flat rate to declare indirect costs:</p>

⁵ The auditor does not need to check indirect costs if they are reported as a flat rate of direct eligible costs.

⁶ Depending on the "certified methodology on *in kind contribution*", the auditor must determine whether procedure n°10 applies.

⁷ Procedure n°11 applies only to *EFPIA companies* using the simplified method (as stipulated in Article II.14.2.a) of the *grant agreement*).

<p>rate to claim indirect costs in accordance with Annex II of the <i>IMI JU grant agreement</i> being reviewed. In such case the procedure to apply is:</p> <ul style="list-style-type: none"> - The auditor confirmed that the flat rate applied on the Financial Statement(s) is consistent with the one provided in Annex II of the <i>IMI JU grant agreement</i>. The auditor recalculated the indirect costs claimed on the basis of the flat rate for <u>arithmetical accuracy</u>. 	<p>The auditor found:</p> <ul style="list-style-type: none"> - that the flat rate has been charged in accordance with Annex II of the <i>IMI JU grant agreement</i> and computed on direct eligible costs excluding costs for sub-contracting and the costs of resources made available by third parties which are not used on the premises of the <i>EFPIA company</i>; - that <u>no differences arose from the numerical reconciliation</u>.
<p>11. Assess use of a simplified method of calculation of overheads at the level of the legal entity. The <i>EFPIA company</i> may use a simplified method of calculation (either due to the lack of analytical accounting or legal requirement to use a form of cash-based accounting). This does not permit the use of a generalised estimate, or the use of a 'standard' rate that is not derived from the accounting records of the period in question. Thus the rate (but not the methodology) should be updated for each accounting period.</p>	<p>The <i>EFPIA company's</i> accounting system does not permit indirect costs to be separately identified for the individual departments</p> <p>[and/ or]</p> <p>The <i>EFPIA company's</i> accounting system is cash-based and year-end adjustments are made using accounting estimates in order to charge certain accrued costs.</p> <p>The Auditor obtained the breakdown of overhead costs and the adjusting entries together with the source of the relevant accounting entries.</p> <p>The <i>EFPIA company</i> provided the Auditor with underlying calculations showing the basis for additional accounting entries. The Auditor agreed these calculations to the relevant sources of management information.</p> <p>Any elements of a simplified calculation which represent percentage estimates and which cannot be compared to underlying data should be listed (together with the amounts) as exceptions in the main report.</p>
<p>Other^{8,9}</p>	
<p>12. Inspect and compare exchange rates into Euros</p>	<p>The Auditor compared the exchange rates used for conversion with the applicable official exchange rates established by the European Central Bank and the <i>EFPIA company</i> used.</p>

⁸ Procedure n°12 does not apply to *EFPIA companies* with accounts in EUR and costs incurred in other currencies

⁹ Procedure n°13, if applicable



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	<p>[choose one / deleted option which is not applicable]</p> <p>[Option 1] the conversion rate of the date where the actual costs were incurred</p> <p>[Option 2] the rate applicable on the first day of the month following the end of reporting period</p> <p>Where rates cannot be agreed, an exception should be noted, (together with the amount) in the main report.</p>
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13. Direct Financial contribution	The auditor checked Financial contributions from <i>EFPIA companies</i> to <i>beneficiaries</i> and found that they were recorded in the accounting system of the <i>EFPIA company</i> and paid directly to the <i>beneficiary</i> . If amounts cannot be reconciled, this should be reported as an exception in the main report.
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[Legal name of the audit firm]

[name and function of an authorised representative of the audit firm]

<dd Month yyyy>

<Signature of the Auditor>