**TERMS OF REFERENCE FOR THE CERTIFICATION BY INDEPENDENT EXTERNAL AUDITORS OF THE FINANCIAL STATEMENTS OF IN KIND CONTRIBUTIONS  
BY EFPIA AND ANY OTHER MEMBERS OTHER THAN THE EUROPEAN UNION AND THE ASSOCIATED PARTNERS UNDER IMI2 JU PROGRAMME**

Contents

[Introduction 2](#_Toc474836063)

[Terms of Reference for the Independent Report of Factual Findings of Agreed-upon Procedures on costs declared as in kind contributions to IMI2 in accordance with the IMI 2 Council Regulation 4](#_Toc474836064)

[Independent Report of Factual Findings on costs declared in relation to *IMI2 JU* grant agreements and/or to IMI2 JU advisory groups foreseen in the Annual Work Plan 7](#_Toc474836065)

[Annex I: Procedures performed by the Auditor 10](#_Toc474836066)

[Annex II: Financial Statements 22](#_Toc474836067)

The "Terms of Reference"should be completed by the BNRF *(*‘Beneficiaries Not Receiving Funding’[[1]](#footnote-2)) and be agreed with the Auditor.

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

# Introduction

In line with the IMI2 Council Regulation (‘the Regulation’) establishing the Innovative Medicines Initiative 2 Joint Undertaking (‘IMI2 JU’)[[2]](#footnote-3), EFPIA and any other Members other than the European Union and Associated Partners, or their constituent entities or their affiliated entities, (hereinafter referred to as ‘Beneficiaries Not Receiving Funding’ or ‘BNRF’[[3]](#footnote-4)) participating in IMI2 JU indirect actions do not receive any financial contribution. Instead, they contribute to the financing of IMI2 JU in the form of the costs incurred by them in implementing these actions[[4]](#footnote-5). Such in kind contributions can be generated either a) In implementing IMI indirect actions (hereinafter ‘projects’) subject to a signed grant agreement; or b) in relation to Advisory Groups such as Strategic Governing Groups, if foreseen in the IMI2 JU Annual Work Plan.[[5]](#footnote-6)

In order for IMI2 JU to account for their in kind contributions, the BNRFs are required to report each year by 31 January to the Governing Board of the IMI2 JU on the value of these contributions made in each of the previous financial years[[6]](#footnote-7). For the purpose of valuing these contributions, the costs shall

1. be determined in accordance with the usual cost accounting practices of the entities concerned, to the applicable accounting standards of the country where the entity is established, and to the applicable International Accounting Standards and International Financial Reporting Standards.
2. be certified by an independent external auditor appointed by the BNRF concerned.[[7]](#footnote-8)
3. be devoted to the objectives set out in Article 2 of the Regulation[[8]](#footnote-9). [[9]](#footnote-10)

The purpose of this document is to set out the Terms of Reference (‘ToR’) for Certification of the Financial Statements (‘the Certification’[[10]](#footnote-11)) to be submitted by BNRFs to IMI2 JU that their declared in kind contributions meet the requirements of the Regulation. It is also meant to help the BNRFs and their auditors in 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 Certification 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 ToR stipulated in this document, 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 Certification is composed of the following **two** separate documents:

1. **The engagement letter** that must be dated and signed by both parties. The IMI2 JU will receive a copy of the engagement letter. *A list of the terms of reference (sections 1.1 to 1.8) required by the IMI2 JU shall be included in the engagement letter between the BNRF and the auditor.*
2. **The Independent Report of Factual Findings of Agreed-upon Procedures**. The report is to be issued on the auditor’s letterhead, dated and signed by the auditor. The IMI2 JU will receive either an electronic copy of the signed original of the report or the electronically signed original report. The original report or a copy shall be kept by the BNRF in accordance with applicable EU and/or national legislation. The report must contain two annexes as follows:

**Annex I: 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 duly filled in by the auditor upon 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 BNRF’s situation and insert any exception noted.

**Annex II: Copies of the financial statements** that are subject to the engagement.

# Terms of Reference for the Independent Report of Factual Findings of Agreed-upon Procedures on costs declared as in kind contributions to IMI2 in accordance with the IMI 2 Council Regulation

*A guide on how to outline the agreement (i.e. engagement letter) between the BNRF and the auditor to provide an independent report of factual findings of agreed-upon procedures on the financial statement[s] prepared by the BNRF.*

*(To be prepared on Auditor’s letterhead paper and addressed to the Beneficiary Not Receiving Funding)*

[Date]

[Salutation]

**Terms of Reference for an Independent Report of Factual Findings on costs declared as in-kind contributions to the Innovative Medicines Initiative 2 Joint Undertaking (“IMI2 JU”) in accordance with Council Regulation (EU) No 557/2014 of 6 May 2014 (“the Regulation”)**

The following are the terms of reference (‘ToR’) on which **<*name of the BNRF>*** (”the BNRF”) agrees to engage **< *name of the audit firm>*** (“the Auditor” or “we”) to provide an independent report of factual findings on [a] financial statement[s][[11]](#footnote-12) (“the Financial Statement[s]”) prepared by the BNRF*,* declaring costs incurred in implementing the IMI2 JU grant agreement(s) (“the Grant Agreements”) and in carrying out work in the IMI2 JU advisory groups[[12]](#footnote-13) (“the Advisory Groups”) that are identified in the Financial Statement[s]. Where in these ToR the ‘IMI2 JU’ is mentioned this refers to its quality as signatory of the Grant Agreement(s) to which the BNRFis a party;and as the entity to which the BNRF submits the Financial Statement(s). For clarification purposes, the IMI2 JU is not a party to this engagement.

**1.1 Responsibilities of the Parties to the Engagement**

‘**The BNRF**'refers to the legal entity that has signed[[13]](#footnote-14) the Grant Agreement(s) listed in the Financial Statement[s] with the IMI2 JU and has declared costs generated under these Grant Agreements and/or has declared costs to IMI2 JU generated in carrying out work in Advisory Groups foreseen in the IMI2 JU Annual Work Plan for the year(s) concerned.

The Grant Agreements and Advisory Groups are detailed in the Financial Statement[s] referred to below in Section 1.2.

* + The BNRF is responsible for preparing a Financial Statement[s] to declare its costs for recording in the accounts of the IMI2 JU as in-kind contributions, generated under a grant agreement in IMI2 JU projects or in advisory groups foreseen in the IMI2 JU Annual Work Plan, and for ensuring that this Financial Statement[s] can be properly reconciled to the BNRF’s accounting and bookkeeping system and to the underlying accounts and records. Notwithstanding the procedures to be carried out, the BNRF remains at all times responsible and liable for the accuracy of the Financial Statement[s].
  + The BNRF 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 BNRF accepts that the ability of the Auditor to perform the procedures required by this engagement effectively depends upon the *BNRF* providing a view of all or parts, as required by the Auditor for the purposes of this engagement, of all relevant IT systems as well as its accounting and other relevant records under this agreement[[14]](#footnote-15), within the limits of applicable EU and/or national laws and regulations[[15]](#footnote-16) on data protection.

‘**The Auditor’** is responsible for performing the agreed-upon procedures as specified in these ToR and for submitting an independent report of factual findings to the BNRF.

The Auditor must be independent from the BNRF.

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.

The procedures to be performed are specified by the IMI2 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 Financial Statement[s] submitted to the IMI2 JU for the period[s] [[16]](#footnote-17) covering

*<****dd Month yyyy to dd Month yyyy****>* and for the total amount of costs of in-kind contributions <**amount in EUR**>;

and

*<****dd Month yyyy to dd Month yyyy****>* and for the total amount of costs of in-kind contributions <**amount in EUR**>

The Financial Statement[s] subject to this engagement, detailing all Grant Agreements and Advisory Groups concerned, shall be attached as Annex II to the Independent Report of Factual Findings.

**1.3 Reason for the Engagement**

The BNRF is required to submit to the IMI2 JU a certification of [a] Financial Statement[s] in the form of an independent report of factual findings of agreed-upon procedures produced by an external auditor in support of the in-kind contribution declared by the BNRF.

**1.4 Engagement Type and Objective**

This constitutes an engagement to perform specific agreed-upon procedures regarding an independent report of factual findings on costs declared to the IMI2 JUin connection with IMI2 JU Grant Agreement(s) and IMI2 JU Advisory Groups, as detailed in the Financial Statement[s]. As this engagement is not an assurance engagement the Auditor does not provide an audit or a review opinion and expresses no assurance.

The IMI2 JU derives its assurance by drawing its own conclusions from the factual findings reported by the Auditor on the Financial Statement(s) and the in-kind contribution of the BNRF relating thereto.

The Auditor shall include in its report that no conflict of interest exists between it and the BNRF in establishing 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 *IMI2 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 the Independent Report of Factual Findings in Annex 1 of these Terms of Reference and uses the evidence obtained from these procedures as the basis for the report of factual findings.

* 1. **Reporting**

The report of factual findings of agreed-upon procedures, in accordance with the International Standard on Related Services (‘ISRS’) 4400, an example of which is attached at Appendix 1 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 BNRF and the IMI2 JU to understand the nature and extent of the procedures performed by the Auditor.

Use of the reporting format (*Independent Report of Factual Findings*) that is described in Annex 1 is compulsory.

In accordance with Art. 4.4 of the Regulation, the valuation method may be verified by the IMI2 JU should there be any uncertainty arising from the certification. In case of remaining uncertainties, it may be audited by the IMI2 JU.

* 1. **Timing**

The Report should be provided by **[DATE**].

* 1. **Other Terms**

[*The BNRF 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 BNRF]***

***[name & function of authorised representative] [name & function of authorised representative]***

***<dd Month yyyy> <dd Month yyyy>***

***<Signature of the Auditor> <Signature of the BNRF>***

# Independent Report of Factual Findings on costs declared in relation to *IMI2 JU* grant agreements and/or to IMI2 JU advisory groups foreseen in the Annual Work Plan

*To be printed on letterhead paper of the Auditor*

**Independent Report of Factual Findings on costs declared in relation to IMI2 JUgrant agreements and/or in relation to IMI2 JU advisory groups foreseen in the Annual Work Plan**

**Private & confidential**

**<Name of contact person(s)>**

**< Position>**

**< *BNRF*’s name>**

**<Address>**

**<dd Month yyyy>**

**[Salutation]**

**Report of [Auditor] to [name of BNRF] of factual findings in relation to costs declared in connection with Innovative Medicines Initiative 2 Joint Undertaking (“IMI2 JU”) grant agreements and/or IMI2 JU advisory groups**

In accordance with our engagement letter (Terms of Reference) dated ***<dd Month yyyy>* (“the ToR”)** with ***<name of*** the *BNRF****>*** (“the BNRF”) (enclosed with this report), we provide our Independent Report of Factual Findings 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], hereinafter referred to as ‘the Auditor’ or ‘we’,*** have performed the agreed-upon procedures set out in Annex I regarding the costs declared in the Financial Statement[s][[17]](#footnote-18) in Annex II herein of **[*name of BNRF*]** hereinafter referred to as the BNRF. This engagement involved performing certain specified procedures agreed with the BNRF, the results of which the IMI2 JU uses to draw conclusions as to the eligibility of the costs declared,for the following period (Dates: dd Month yyyy - dd Month yyyy) and the following total amount of costs of in kind contributions EUR XX (insert amount in numbers and letters).[[18]](#footnote-19)

**Scope of Work**

Our engagement was carried out in accordance with:

* the ToR enclosed with 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 *IMI2 JU* 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 ToR for this engagement and we have reported our factual findings on those procedures in the table in Annex I to this Report.

The scope of these agreed upon procedures has been determined solely by the IMI2 JU and the procedures were performed solely to assist the IMI2 JU in evaluating whether the costs declared by the BNRF in the accompanying Financial Statement(s) have been declared in accordance with the Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking (‘the Regulation’). 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 Statement(s).

Had we performed additional procedures or had we performed an audit or review of the Financial Statement(s) of the BNRF in accordance with International Standards on Auditing or International Standards on Review Engagements, 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 BNRF in response to specific questions or as obtained and extracted from the BNRF’s information and accounting systems.

**Factual Findings**

The above mentioned Financial Statement[s] was (were) examined and all procedures specified in Annex I 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 BNRF. 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 listed in Annex I below, etc. must be listed here. Where the exception is quantifiable, the amount concerned must be mentioned. The IMI2 JU will use this information to decide the amounts which will be accepted as contribution.***

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| **Procedure** | **Description of the exception; the description should include a reference to the project concerned or a mention that the cost is related to Advisory Groups** | **Where quantifiable, amount(s) concerned (- when initially overstated / + when initially understated) [[19]](#footnote-20)** |
|  |  | +/- |
|  |  | +/- |

**Use of this Report**

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

This Report is prepared solely for the confidential use of the BNRF and the IMI2 JU and solely for the purpose of submission by the BNRF to the IMI2 JU in connection with the requirements as set out in Articles 4.3 and 4.4 of the Regulation. This Report may not be relied upon by the BNRF or by the IMI2 JU for any other purpose, nor may it be distributed to any other parties. It has been prepared in accordance with our engagement letter dated [ DATE], a copy of which is attached, and the terms of which shall apply as if set out in full in this report. Particular attention is drawn to the provisions therein for the limitation of our liability to both intended recipients of our report.

Without assuming or accepting any responsibility or liability in respect of this Report to any party other than the BNRF and the IMI2 JU, we acknowledge that the IMI2 JU may be required to 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 BNRF.

No conflict of interest[[20]](#footnote-21) exists between the Auditor and the BNRF in establishing this Report.

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

Yours faithfully

***[Legal name of the audit firm]***

***[Name and function of an authorised representative]***

***<dd Month yyyy>***

***<Signature of the Auditor>***

# Annex I: Procedures performed by the Auditor

**Procedures performed by the Auditor for BNRF**

The Auditor designs and carries out his work in accordance with the objective and scope of this engagement and the agreed-upon procedures to be performed as specified below (‘the Procedures’). The scope of the Procedures was defined by the IMI2 JU and agreed with the BNRF. Therefore, the Auditor is not responsible for their suitability or pertinence. When performing the 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.

**For each of the procedures carried out, the Auditor should first acquire from the BNRF, via documentation and enquiries, an understanding of the usual practice and standards of the BNRF as regards their cost accounting. The procedures should then be carried out with reference to these standards.**

**For each section A-F, unless otherwise stated in the list of procedures below, a random sample of relevant units should be drawn across all projects/Advisory Groups. The sample should be of full coverage if less than 10 items, otherwise a sample of minimum 10, or 10% of the items, whichever is the greater.**

| **Rationale** | **Procedures** | **Standard factual finding and basis for exception reporting** |
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| **A.1 Personnel costs – productive hours and hourly rate** | | |
| The auditor should select a sample of personnel randomly so that it is representative of all declared personnel costs across all projects and Advisory Groups and includes non-EU costs if the latter are declared in the Financial Statement(s).  Full coverage is required if there are fewer than 10 people, otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest.  The Auditor sampled \_\_\_\_\_people out of the total of \_\_\_\_\_\_people.  Procedures 1-4 below should be carried out on the above sample as applicable. | | |
| 1. To recalculate the number of productive hours and the personnel cost rates applied for the cost declaration to be in line with the BNRF’s usual cost accounting standards. | Obtain an understanding of the BNRF’s methodology for calculating their personnel cost rates. Indicate the total 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 recalculated the productive hours. 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 BNRF). | The productive hours calculation corresponds to the usual accounting practice of the BNRF.  **If the productive hours or costs of personnel cannot be recalculated, 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.** |
| **A.2 Personnel costs – FTE rate** | | |
| 1. Where average personnel cost rates are used, to recalculate the rates applied for the cost declaration to be in line with the BNRF’s cost accounting practice. | • The Auditor inspected all relevant manuals/processes and/or internal guidance describing the methodology used to calculate average personnel costs.  • The Auditor obtained a list of the average personnel rates calculated by the BNRF in accordance with the methodology used.  • The Auditor obtained the personnel cost data based on which the average personnel rate(s) are calculated.  • The Auditor inspected the allocation of employees to the potential relevant group and reconciled them to the average Full Time Equivalent (FTE) rate for the BNRF where this is applicable.  • 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 recorded in the in the accounting system and/or other enterprise resource systems, as applicable according to the usual methodology of the BNRF for the reference year.  • The Auditor reconciled on a sample basis the appropriate average hourly rate used for the personnel costs declared on the Grant Agreement(s) and Advisory Group(s) listed subject to this engagement. | |  | | --- | | The Auditor found:  - no discrepancies between the method described in the relevant documents and the method used by the BNRF;  - the methodology used to calculate the average personnel hourly rate(s) represents the usual cost accounting practice of the BNRF;  - no differences arose from the numerical reconciliation.  **If amounts cannot be reconciled, this should be reported as an exception in the main report.**  **If the FTE rates applied in the Financial Statement(s) are not calculated in accordance with the accounting practice, this should be reported as an exception in the main report together with the amounts concerned.** | |

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| **A.3 Personnel costs – allocation of costs to IMI activities** | | |
| 1. Personnel time included in the declaration of expenses must be recorded in accordance with the BNRF‘s usual practice, traceable back to IMI project(s)/Advisory Group(s) activities. This is to verify that all expenses declared have actually been devoted to the objectives of IMI2 JU.[[21]](#footnote-22) In case of costs declared in relation to IMI projects subject to a Grant Agreement, these must be linked to the implementation of the action tasks attributed to the BNRF in Annex 1 of the Grant Agreement and according to Article 7.1.of the Grant Agreement. In case of costs declared in relation to Advisory Groups foreseen in the annual Work Plan these must be directly linked to tasks carried out for those groups. | The Auditor obtained documentation from the BNRF on its usual time recording system and practice.  The Auditor examined and described **time recording** (paper/ computer, daily/weekly/monthly, signed, authorised).  For a sample of employees selected at random, the Auditor checked that   * employees have recorded their time according to usual BNRF practice; * employees have recorded the time spent on IMI2 JU project and/or Advisory Groups activities;   In cases where the BNRF in line with its usual practice does not retain the detailed time records for reasons of e.g. internal data privacy/protection rules, the Auditor should conduct alternative procedures to ensure the reliability of the attribution of the personnel costs to the project in the BNRF’s project accounting, and document these alternative procedures and related findings in the report.  Where only anonymised timesheets/timesheets at an organisational unit level are available, the Auditor should reconcile these with the details recorded in the BNRF’s final project accounting to ensure the completeness, accuracy and validity of the time recording, and document these alternative procedures and related findings in the report.  For costs declared on Advisory Group activities:  - the Auditor reconciled the groups mentioned in the Financial Statement(s) to the IMI2 JU Annual Work Plan. | Employees record their time on a **[daily/ weekly/ monthly]** basis using a **[paper/computer]**-based system.  Time records for the sample clearly show the time spent on IMI2 JU project/Advisory Group activities.  **or**  Alternative procedures allow for a reconciliation between the personnel costs declared and the project/Advisory Group activities.  Advisory Groups for which personnel costs are declared are identified in the *IMI2 JU* Annual Work Plan.  **If time recording does not comply with the BNRF’s usual practice and/or the time declared cannot be traced back to project/Advisory Group activities, this should be recorded as an exception in the main report.** |
| 1. Personnel costs are recorded in accordance with the BNRF’s usual practice; incurred in the period of the Financial Statement; and the personnel costs are reported correctly as having been generated either in the EU and H2020 Associated Countries or outside these countries. | **Employment status** and employment conditions of personnel. The Auditor should obtain proof of employee engagement (e.g. 1.contracts, 2. HR records, 3. social contributions, 4. prerequisite to be employed to record time in the time recording system or similar) of the employees selected to establish that the people were employed in line with BNRF practice at the time when costs related to their work on IMI projects/Advisory Groups is declared.  **The checks carried out must be described in the report of factual findings.**  The auditor reconciled the place of employment of the sampled employees to the project accounting records as being either in the EU and H2020 Associated Countries or outside these countries. | For the employees selected, the Auditor carried out procedures as described in the report of factual findings and found that:  - they were employed at the time of the period of the Financial Statement.  - their place of employment corresponded to the reporting of the personnel costs in the Financial Statement as generated either in the EU and H2020 Associated Countries or outside these countries.  **Amounts for personnel who were not employed should be listed as exceptions in the main report.   Amounts for personnel whose place of employment did not correspond to the reporting of the costs in the Financial Statement as EU/non-EU should be listed as an exception in the main report.** |
| **B. Subcontracting** | | |
| The Auditor obtained the detail/breakdown of subcontracting costs. The Auditor sampled\_\_\_\_\_\_ cost items selected randomly, including non-EU subcontracting costs in the sample if the latter were reported in the Financial Statement(s).  Full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 items, or 10% of the total, whichever number is highest. | | |
| 1. Subcontracting is done in line with the BNRF’s usual internal practice. and the subcontracting costs are reported correctly as being generated either in the EU and H2020 Associated Countries or outside these countries.   Note: This procedure refers only to subcontracting that   * Relates directly to project tasks as described in the Description of Action (Annex I). * Is not considered minor according to the BNRF’s internal procedure, i.e. requires a procurement procedure * Is not part of the FTE rate.   All other subcontracting falls under procedure 7. | Read documents and obtain confirmations from the BNRF that subcontracts are awarded according to the usual internal practice of the BNRF.  Obtain the description of action (Annex I to the Grant Agreement) and compare that description to the subcontracts or, if the subcontracted tasks are not mentioned in the Annex I, check that a brief description of the subcontracted tasks is provided in the Financial Statement.  Reconcile project accounting records to invoices issued by counterparties performing their services in the EU and H2020 Associated Countries on the one hand, and on the other hand to invoices issued by counterparties performing their services outside these countries. | The Auditor obtained the relevant documentation for each subcontract entered into and found that the usual internal practice was followed by the BNRF in support of the final choice of subcontractor.  **If the Auditor  - is not provided with evidence that the subcontracting was carried out in line with usual internal practice  - notes that the subcontracts were not mentioned in the description of action nor in the Financial Statement  - cannot reconcile project accounting records to invoices issued by counterparties performing their services in the EU and H2020 Associated Countries on the one hand, and on the other hand to invoices issued by counterparties performing their services outside these countries.   The amount of the subcontract should be listed as an exception in the main report.** |

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| **C. Other direct costs** | | |
| **C.1 Costs of travel and related subsistence allowances** | | |
| **The Auditor sampled\_\_\_\_\_\_ cost items selected randomly. Full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest.** | | |
| 1. Travel and subsistence costs are recorded in accordance with the BNRF’s usual practice, linked to the IMI activity and incurred in the period of the Financial Statement. | Note: Where all travel and subsistence costs are included in the FTE rate according to the BNRF’s usual cost accounting practice, this procedure is not applicable.    The Auditor checked that:  - travel and subsistence costs were consistent with the BNRF’s usual policy for travel. In this context, the BNRF provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the BNRF on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy;  - travel costs are correctly identified and allocated to the IMI project (e.g. trips are directly linked to the action) by inspecting relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference. | If the Auditor finds that the travel and subsistence costs in the sample were  -not in accordance with the usual cost accounting practice of the BNRF;  - not reconcilable to IMI project activity as described in the description of action (Annex I to the Grant Agreement) or a meeting of an Advisory Group;  - not procured in the period of the Financial Statement;   The corresponding amounts should be listed as an exception in the main report. |

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| **C.2 Costs of other goods and services** | | |
| The Auditor sampled \_\_\_\_\_\_cost items selected randomly. Full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 items, or 10% of the total, whichever number is highest. | | |
| 1. Purchase of goods, works and services for the project in accordance with the BNRF’s usual practice, allocated correctly to the IMI activity and incurred in the period of the Financial Statement.   Note: Subcontracting of actual core project work as described in the Description of Action (Annex I) is not covered under this procedure. It falls under procedure 5. | Note: Where all purchased goods, works and services are included in the FTE rate according to the BNRF’s usual cost accounting practice, this procedure is not applicable.  For the purchase of goods, works or services included in the sample the Auditor checked that   * these goods and services were acquired in conformity with the Beneficiary's internal guidelines and usual cost accounting practices; * they were linked to the project as described in the description of action (Annex I to the Grant Agreement); * the goods were not placed in the inventory of non-current assets;   (Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, specific evaluation of the action if it is required by the Grant Agreement, certification of financial statements, translations, reproduction.) | If the Auditor finds that the goods, works and services in the sample were  -not procured in accordance with the usual cost accounting practice of the BNRF;  - not reconcilable to IMI project activity as described in the Description of Action (Annex I to the Grant Agreement) or the work of an Advisory Group  - not procured in the period of the Financial Statement; - the goods were placed in the inventory of non-current assets;   The corresponding amounts should be listed as an exception in the main report. |
| **C.3 Depreciation costs for equipment, infrastructure or other assets** | | |
| The Auditor sampled \_\_\_\_\_\_cost items selected randomly. Full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 items, or 10% of the total, whichever number is highest. | | |
| 1. Valuation and allocation of costs of equipment to the project is in accordance with the BNRF‘s usual cost accounting practice and correctly allocated to IMI project activities. | Note: Where all purchased equipment is included in the FTE rate according to the BNRF’s usual cost accounting practice, this procedure is not applicable.    The Auditor checked that **equipment,** subject to depreciation, is correctly identified and allocated to the IMI project tasks. | The Auditor traced the equipment charged to the project to the BNRF’s accounting records and the underlying invoices. The BNRF has documented the link with the project. The asset value was agreed to the invoice. The depreciation method used to charge the equipment to the project was compared to the BNRF's usual cost accounting practice 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.** |

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| **D. Indirect costs** | | |
| 1. Identification and allocation of indirect costs to the project is in accordance with the BNRF‘s usual cost accounting practice. | Note: Where all indirect costs are included in the FTE rate according to the BNRF’s usual cost accounting practice, this procedure is not applicable.    The Auditor obtained an understanding of the usual cost accounting practice of the BNRF with regard to indirect costs.  The Auditor obtained the total overhead amount which was allocated and reconciled this to the accounting records for the period in question.  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 BNRF] and agreed it to the rate used in the cost declaration.  The Auditor obtained a breakdown from the accounting system of the indirect costs which have been charged to the project(s), and reconciled the individual amounts to the general ledger of the BNRF.  The Auditor checked that only indirect costs that were allocated to IMI activities in accordance with the BNRF’s usual practice were included in the Financial Statement(s). | Identification and allocation of indirect costs to the project is in accordance with the BNRF‘s usual cost accounting practice.  Indirect costs for non-research activities are not included in the cost declaration if not being part of the BNRF’s usual cost accounting practice. Where indirect costs are reported separately, they are not included in the FTE rate calculation.  **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.** |

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| **E. Exchange rates** | | |
| **The Auditor sampled\_\_\_\_\_\_cost items selected randomly and verified that the exchange rates used for converting other currencies into euros are in line with the BNRF’s usual cost accounting practice.** | | |
| 1. Check whether exchange rates applied are in line with the BNRF’s usual cost accounting practice. | On a sample basis, the Auditor checked if the used exchange rates into Euros followed the BNRF’s usual cost accounting practice. | Exchange rates applied in the sample were found to be in line with the BNRF’s usual cost accounting practice.  **Where rates cannot be agreed, an exception should be noted, (together with the amount) in the main report.** |
| **F. Financial contributions** | | |
| 1. Direct financial contributions declared in the Financial Statement(s) can be reconciled to invoices/payment requests and service agreements | The Auditor obtained a list of *all* items of direct financial contributions declared in the Financial Statement and reconciled the amounts to the accounting system of the BNRF.  The Auditor was presented with an agreement for each financial contribution that explicitly established the BNRF providing the contribution as well as the beneficiary receiving it and was signed by both parties; established the amount of the contribution; and the IMI2 JU project, tasks and deliverables for which the contribution is to be used by the recipient. Provided that the above conditions are fulfilled, such agreement may be constituted by the Grant Agreement, in particular Annex I thereto; the Consortium Agreement; or a bilateral or multilateral agreement.  The Auditor was presented with an invoice/request for payment detailing the counterparty, amount, project details, tasks and deliverables, **corresponding to the description of action (Annex I to the Grant Agreement).** | Each financial contribution declared can be reconciled to the accounting system of the BNRF.  For each financial contribution, there is a formal agreement (i.e. Grant Agreement detailing the contribution; Consortium Agreement detailing the contribution; or a bilateral/multilateral agreement)between the BNRF and the recipient as well as an invoice, each of which explicitly establishes the amount of the contribution, which must correspond to that declared in the Financial Statement, as well as indication of the IMI2 JU project tasks for which this amount is to be used by the recipient and specific deliverables.  **Exceptions, together with amounts, must be noted in the main report where:**   * **Direct financial contributions declared cannot be reconciled to the accounts;** * **The payment amount does not correspond to the amount declared in the Financial Statement** * **There is no formal agreement for a financial contribution or the agreement does not explicitly state all the above-mentioned details;** * **There is no invoice/request for payment for a financial contribution or the invoice/request for payment does not explicitly state the recipient of the contribution, the amount, the IMI2 JU project, tasks and deliverables to which it is to be used, corresponding to the description of action (Annex I to the Grant Agreement) and to the specific agreement for the direct financial contribution where applicable.** |

# Annex II: Financial Statements

*The Financial Statement(s) subject to this assignment shall be attached here*

1. In this guidance, the term ‘BNRFs’ only refers to beneficiaries not receiving JU funding which are JU Members other than the Union and of the Associated Partners, or their constituent entities or their affiliated entities. [↑](#footnote-ref-2)
2. Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking [↑](#footnote-ref-3)
3. In this guidance, the term ‘BNRFs’ only refers to beneficiaries not receiving JU funding which are JU Members other than the Union and of the Associated Partners, or their constituent entities or their affiliated entities. [↑](#footnote-ref-4)
4. Statutes, Regulation (EU) No 557/2014: Art.13.1 The IMI2 Joint Undertaking shall be jointly funded by the Union, the Members other than the Union and the Associated Partners, or their constituent entities or their affiliated entities through financial contributions paid in instalments and contributions consisting of the costs incurred by them in implementing indirect actions and that are not reimbursed by the IMI2 Joint Undertaking. [↑](#footnote-ref-5)
5. Statutes, Regulation (EU) No 557/2014: Art.13.3.b. Please refer also to the Charter of the IMI2 Strategic Governing Groups (SGG) approved by the Governing Board and annexed to its Decision ref. IMI2-GB-DEC-2014-2 of 7 July 2014 setting up the first groups. [↑](#footnote-ref-6)
6. Regulation (EU) No 557/2014: Art.4.3: e Members other than the Union and Associated Partners shall report each year by 31 January to the Governing Board of the IMI2 Joint Undertaking on the value of the contributions referred to in paragraph 2 made in each of the previous financial years. The States Representatives Group shall also be informed thereof in a timely manner.

   [↑](#footnote-ref-7)
7. Regulation (EU) No 557/2014: Art.4.4: For the purpose of valuing the contributions referred to in point (b) of Article 13(3) of the Statutes, the costs shall be determined in accordance with the usual cost accounting practices of the entities concerned, to the applicable accounting standards of the country where the entity is established, and to the applicable International Accounting Standards and International Financial Reporting Standards. The costs shall be certified by an independent external auditor appointed by the entity concerned. The valuation method may be verified by the IMI2 JU should there be any uncertainty arising from the certification. In case of remaining uncertainties, it may be audited by the IMI2 JU Joint Undertaking. [↑](#footnote-ref-8)
8. Statutes, Regulation (EU) No 557/2014: Art.13.5: All resources of the IMI2 JU Joint Undertaking and its activities shall be devoted to the objectives set out in Article 2 of this Regulation. [↑](#footnote-ref-9)
9. In case of costs declared in relation to IMI projects subject to a Grant Agreement, these must be directly linked to the implementation of the action tasks attributed to the BNRFs in Annex 1 of the Grant Agreement and according to Article 7.1. of the Grant Agreement. In case of costs declared in relation to advisory groups foreseen in the annual Work Plan these must be directly linked to tasks carried out for those groups. [↑](#footnote-ref-10)
10. ‘Certification’ consist of the engagement letter and the Independent Report of Factual Findings of Agreed-upon Procedures including its annexes [↑](#footnote-ref-11)
11. Financial Statement in this context refers solely to the Financial Statement (i.e. the form) by which the *BNRF* declares costs to IMI2JU under IMI2 JU grant agreements and/or costs incurred in relation to IMI2 JU advisory groups, if foreseen in the Annual Work Plan. [↑](#footnote-ref-12)
12. See *IMI2 JU* Annual Work Plan as well as the Charter of the IMI2 Strategic Governing Groups (SGG) approved by the Governing Board and annexed to its Decision ref. IMI2-GB-DEC-2014-2 of 7 July 2014 setting up the first groups. [↑](#footnote-ref-13)
13. The BNRF does not sign on the grant agreement itself; it adheres to the grant agreement by signing an accession form to this effect. [↑](#footnote-ref-14)
14. The BNRF may request that the auditors be accompanied by the responsible BNRF employees [↑](#footnote-ref-15)
15. E.g. employees’ right to codetermination [↑](#footnote-ref-16)
16. Where there are several years covered in the Financial Statements subject to this engagement, each annual period should be included here separately with the corresponding amount [↑](#footnote-ref-17)
17. Financial Statement in this context only refers to the Financial Statement by which the *BNRF* declares costs generated under IMI2 JU grant agreements and/or in relation to IMI2 JU Advisory Groups foreseen in the Annual Work Plan to be recorded as in-kind contributions for the IMI2 JU programme. [↑](#footnote-ref-18)
18. Where there are several years covered in the Financial Statements subject to this engagement, each annual period should be included here separately with the corresponding amount [↑](#footnote-ref-19)
19. E.g. where the BNRF has reported 100 EUR in its Financial Statement to IMI2 but the auditor can confirm only 80 EUR, -20 EUR should be noted in the table. Where the BNRF has reported 100 EUR but the auditor can confirm 120 EUR, +20 EUR should be noted. [↑](#footnote-ref-20)
20. A conflict of interest arises when the Auditor’s objectivity to establish the certification is compromised in fact or in appearance when the Auditor for instance:

    Was involved in the preparation of the Financial Statements;

    Stands to benefit directly should the certification be accepted;

    Has a close relationship with any person representing the BNRF;

    Is a director, trustee or partner of the BNRF;

    Is in any other situation that compromises his or her independence or ability to establish the certification impartially. [↑](#footnote-ref-21)
21. Statutes, Regulation (EU) No 557/2014: Art.13.5: All resources of the IMI2 Joint Undertaking and its activities shall be devoted to the objectives set out in Article 2 of this Regulation. [↑](#footnote-ref-22)