



Amendments Guide for IMI Grant Agreements

This guide applies to Grant Agreements signed for projects selected under Call 1-11 of IMI JU, launched between 2008 and 2013.

Version 1.0

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1. Introduction

The purpose of this document is to provide guidance, based on experience, to participants of IMI projects on how to amend the Grant Agreement (GA) signed with the Innovative Medicine Initiative Joint Undertaking (IMI JU). The guide describes the amendment procedure, the different types of amendments and provides examples of wording for the model request letters. Additionally, the guide provides key information in relation to the use of the SOFIA IT tool, the IMI tool to be used for submitting information throughout the whole project life-cycle.

This guide applies to Grant Agreements signed for projects selected under Call 1-11 of IMI JU, launched between 2008 and 2013.

What is an amendment?

An amendment to a GA is a legal act modifying the original commitment between the parties. During the lifetime of the GA, amendments may create new rights, impose new obligations, or modify some of its parts.

As a general rule, an amendment is necessary whenever the original GA has to be modified. This is typically the case for changes of the data included in the core part and/or modification to the Annex I – Description of Work (DoW).

Main characteristics of an amendment

- It is done in writing.
- It enters into force after the signature by the Project Coordinator (COO) and, in some cases, the Managing Entity (ME) receiving the IMI funding and IMI JU.
- It takes effect on the date agreed by the parties; if no date specified, on the date of IMI JU's signature (it has no retroactive effect unless agreed by the parties).
- It can only be implemented after the entry into force of the GA and before the final payment is made.
- It has to be signed by authorising representatives having the same capacity to represent the legal entity as those who signed the initial GA.
- All the other provisions of the GA not affected by the amendment remain unchanged and continue to have full effect.
- After its approval, the amendment becomes an integral part of the GA.
- It has to be in compliance with the rules applicable to the GA (IMI Financial Rules, IMI Rules for Participation) and with the Articles of the GA (e.g. Annex II – General Conditions of the GA).
- It cannot have the purpose or the effect of making changes to the GA which might call into question the original decision awarding the grant or result in unequal treatment of the participants.

Normally, the amendment is formalised through a formal exchange of letters

- a letter-request from the COO on behalf of the consortium, and
 - a letter of acceptance from IMI JU
- **or, in some specific cases, with the joint signature of the same amendment document** by the COO, the ME and the IMI JU (i.e. *amendment initiated by IMI*). This applies to

cases concerning the revision of the model GA, the integration of the selected ENSO proposal into an on-going GA, or inclusion of new/additional EFPIA non-EU in-kind contribution.

2. IMI SOFIA IT tool

The SOFIA (Submission OF Information Application) is the IMI electronic tool to be used for submitting information during the whole project life-cycle, from the submission of the proposal application (Expression of Interest, Full Project Proposal and grant negotiation) until the end of project implementation, including the submission of amendments, and periodic and final reports. Here different types of on-going IMI projects information are stored concerning participants (such as legal, administrative, financial) or project related (i.e. work-packages, milestones and deliverables). This information may become critical during the project implementation when IMI JU needs to get in contact with consortia or specific participants.

For this reason, during project implementation the information included in the SOFIA IT tool should be constantly updated. This may happen, by means of:

- A version session to only update/modify administrative information (such as participants' legal information and representatives, staff and related contact details etc.). IMI opens a 'version session' in the SOFIA IT tool upon the consortium's request from the COO. No additional formalities are required. Once all the modifications are encoded, the session is closed by the COO pushing 'finalise and submit to IMI'. (Please also see section 3.1)
- An amendment session, at any time when significant elements of the GA (such as consortium composition, budget allocation, work-packages, deliverables etc.) need to be formally modified. Any relevant information needs to be reflected in the SOFIA IT tool as well. The update/modification is possible once IMI has opened an 'amendment session' in the SOFIA IT tool upon the consortium's request submitted by the COO.

It is advisable to start encoding the modifications in SOFIA while working on the changes in Annex I - DoW, i.e. prior to the formal submission of the amendment to IMI JU.

Please note that an amendment can only be accepted by IMI when the relevant information is updated in SOFIA. At this point modifications are accepted by IMI together with the formal acceptance of the respective amendment.

Please also note that no more than one amendment per project can be opened at the time in SOFIA.

3. Changes not requiring an amendment - Information procedure

The GA may be affected by changes which do not constitute an amendment because they do not depend on the mutual agreement of the parties. However, this should be communicated to the consortium or to IMI JU in writing, either by information letter or email, depending on the specific case.

It is important to remember that **it is a legal obligation of each participant** (GA Article II.3 f) to inform IMI of any legal or organisational change. In most cases, to comply with this obligation, it is sufficient to update the participant profile in SOFIA (Forms A2.1, 2, 3, 4).

For these reasons, the COO is responsible for ensuring that the information provided in SOFIA is maintained and up-to-date. To do so, all the members of the consortium should be aware that anytime a modification occurs in their data originally provided in SOFIA, this should be updated accordingly. This should be done following consultation with IMI.

Changes can be classified as follows:

3.1 Changes that only need an update of information encoded in SOFIA

Some modifications/updates of administrative information can be done by simply updating the relevant participant profile in the IMI IT SOFIA tool. Please note that this only refers to purely administrative changes (Form A2.4 – for example- contact person for scientific and/or legal aspects, or contact details etc.). It is strongly advisable that each participant first consult the COO or IMI (by e-mail) to ensure that the said changes fall in this category.

These changes can be performed either as part of an ongoing amendment, or if necessary, on their own:

- a) When an amendment is on-going (for example - during an open session in SOFIA), the COO can invite participants to update their profile in SOFIA;
- b) When necessary and if there is no amendment open, the COO should request IMI to open a version in SOFIA to invite participants to update their profile (only for changes having no impact on the signed GA, thus not requiring an amendment)
- c) One additional option is reserved to EFPIA companies - ILG members¹. They can modify their company administrative information across projects under open amendments/versions or by requesting the opening of a new version session².

3.2 Changes that require an update of the information in SOFIA and of the PDM-URF information.

At any time a change concerns legal data (Form A2.1 - e.g. legal address, legal name etc.) in parallel to updating SOFIA, the concerned participant (via the LEAR - *legal entity appointed representative*) should also inform the competent European Commission service called the *Unique Registration Facility/Participant Data Management (URF/PDM)* to update the information linked to its Participant Identification Code (PIC number) using the following link:

<http://ec.europa.eu/research/participants/portal/desktop/en/funding/index.html>

or via the functional mailbox:

REA-URF-VALIDATION@ec.europa.eu

¹ Industry Liaison Group composed by EFPIA companies' representatives.

² In which case, the respective coordinator will be automatically notified by SOFIA.

Please first consult with the IMI Office who can help and give advice to speed up the procedure with the PDM-URF

3.3 Changes that require a formal notification to IMI, an update of the information in SOFIA and of the PDM-URF information.

Change of legal representatives: at any time the identity of the authorised representatives mentioned in the GA (and in SOFIA under Form A2.3) changes, a signed information letter should be sent to IMI (scanned pdf by email is sufficient).

Universal transfer of rights and obligations: (in case of a take-over or merger) this needs to be notified to IMI by means of a formal communication and an update of relevant information in the SOFIA IT tool and to the URF/PDM by the submission of the relevant supporting documents about the transfer of rights and obligations.

PLEASE NOTE: *an amendment will be necessary for cases where the participant concerned is the COO/ME of the project and some relevant parts of the GA will need to be updated accordingly (see section 5.4).*

4. Amendment request – how to submit an amendment

A Consortium shall ask for an amendment when any of the situations mentioned in sections 5 and 6 occur. The amendment request is submitted by the COO on behalf of the whole consortium. It is the COO's responsibility to ensure that such a request has been adopted by the consortium according to the internal procedure agreed in the Project Agreement.

An amendment initiated by the Consortium is only formally submitted when the original letter of request is received by IMI. The request letter should be signed by the legal representative of the COO, as indicated in the IMI SOFIA IT tool, and addressed to the Executive Director, IMI JU.

In order to trigger the IMI internal approval process, the request must be 'complete', that is it should be accompanied by all relevant supporting documents, and updates should have been made in the SOFIA IT Tool if necessary.

However, in order to facilitate the amendment process the following steps are recommended:

1. The COO informally contacts the IMI scientific officer (SO) in charge of the project, outlining the main elements/reasons for the planned amendment.
2. IMI opens a new amendment session in SOFIA. The consortium will then be able to encode the proposed updates/modifications, such as participants' information, budget tables etc.
3. The COO should submit a draft Annex I - DoW in track changes, together with an explanation/justification and a draft amendment request letter to the appropriate IMI SO by email

4. The IMI SO provides comments or requests modifications. Once a common agreement (between IMI and the consortium) is reached, the IMI SO requests the formal submission of the amendment by the COO.
5. The COO sends the original signed amendment request by surface mail to the IMI Executive Director, and submits (*'finalise and submit to IMI'*) the open amendment session which should include, if necessary, the upload of the final dated Annex I - DoW in PDF format in the SOFIA IT tool.
6. Following the internal IMI approval process, the IMI acceptance letter is signed by the IMI Executive Director and sent to the COO by email and surface mail to the address indicated in the GA (art.8).
7. The submitted amendment session is accepted by IMI in SOFIA IT tool.

5. Type of changes in consortium composition

5.1 Addition of participant (s)/beneficiary (ies)

When an additional organisation joins the consortium, it needs to be added to the list of participant(s)(GA art.1.1)/beneficiary(ies)(GA art.1.5).

This normally happens when:

- a scientist participating in the project moves from one participant to an organisation which is not part of the consortium yet;
- the consortium needs to involve additional expertise not available within the existing participants;
- one withdrawing participant needs to be replaced.

Supporting documents and actions to be completed
<ul style="list-style-type: none"> • Amendment request: letter from COO, on behalf of consortium, justifying and agreeing participation of new participant/beneficiary & indicating the start date. The impact on the project should be explained. The operational capacity of the new participant/beneficiary for carrying out the assigned tasks should be demonstrated.
<ul style="list-style-type: none"> • If a <i>competitive call</i> was foreseen in the Annex I - DoW or in the Call for proposals in order to involve additional beneficiaries, a brief description of the process followed is required. • If a competitive call has not been carried out, a justification for the selection of that beneficiary is required.
<ul style="list-style-type: none"> • The new participant should be added in SOFIA including an indication of the 'activation date', being the starting date of participation in the project as it is mentioned in the request letter and Form B. • Administrative Forms A2.1/.2/.3/.4 duly completed in SOFIA and A2.5 signed by the legal representative of the new participant(s)/beneficiary(ies)
<ul style="list-style-type: none"> • Form B from new new participant(s)/beneficiary(ies) duly signed by the COO and new participant(s)/beneficiary(ies) indicating the same date as in the COO's request and SOFIA 'activation date'.

- | |
|--|
| <ul style="list-style-type: none"> • Upload in SOFIA a modified Annex I - DoW (including a revised budget breakdown A3.2 form from SOFIA); the modified Annex I – DoW must be dated. |
| <ul style="list-style-type: none"> • The participant must have been validated in PDM – (PIC)³
In order to be a beneficiary the organisation must have been validated with a legal status (i.e. SME, non-profit research, public body etc.) which makes it eligible for IMI JU funding according to IMI JU <i>Rules for Participation</i>. • FVC: Legal and financial documents of the new beneficiary, where required⁴ |

Example of request:

The following entit[y][ies] [[is][are]] added as participant[s] with effect from the date[s] specified in the following table:

Full name and legal form of the participant (national registration number if any) established in (full address city/state/province/country), represented by (name of legal representative), (function), [and/or (name of legal representative), (function)], or her/his/their authorised representative ('participant no. XX')	Start date of participation
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[Article 1.1][Page 1] of the GA is modified accordingly.

When the new participant(s) is/are also [a]beneficiary(ies):

Article 1.5 is supplemented as follows:

- *Full name and legal form of the beneficiary ('participant no. XX')*

5.2 Termination of participation

5.2.1 Cases where participant requests termination in agreement with the consortium

The most common case is the termination of the participation requested by the consortium, with the agreement of the participant concerned.

If the participant is a beneficiary, and there is an amount of IMI funds which has to be reimbursed by this beneficiary (for example pre-financing), it is assumed that the beneficiary has already reimbursed the consortium the full amount due or will do it as soon as possible. In such a case, no action from IMI JU is required to recover this amount. Together with the request, the COO should confirm that this amount is at the disposal of the consortium and under its responsibility.

In any other case, for example, when the beneficiary concerned does not agree, or it is not in a position to reimburse (e.g. bankruptcy), this should be explained in the request and additional actions may be required in agreement with IMI JU.

³ If the new participant is not already registered in the Unique Registration Facility (PDM-URF, the participant must self-register, at <http://ec.europa.eu/research/participants/urf>

⁴ The documents necessary for the financial viability check

Supporting documents and actions to be completed
<ul style="list-style-type: none"> Letter from COO, on behalf of consortium, justifying and agreeing termination of participant with the proposed date on which termination shall take effect (i.e. 'termination date'). The impact on the project should be explained.
<ul style="list-style-type: none"> Letter (or alternative means) of agreement of participant leaving consortium (if bankrupt, letter from the bankruptcy administrators).
<ul style="list-style-type: none"> Form C from the leaving participant ⁵ + CFS if applicable covering costs incurred up to the last date of participation (i.e. 'termination date'). Form C shall indicate the same termination date as in the COO's request.
<ul style="list-style-type: none"> Other deliverables referred to in Art.II. 4 relating to the work carried out by the participant together with the comment of the COO on these deliverables and a declaration on distribution of payments to this beneficiary.
<ul style="list-style-type: none"> In SOFIA under the termination of a participant the 'termination date' should be indicated this being the last day of participation in the project as it is mentioned in the request letter. Upload in SOFIA a modified GA Annex I - DoW describing the work (including a revised budget breakdown, Form A3.2 from SOFIA); the modified Annex I - DoW must be dated.

Example of request:

The participation of the following [participant[s] or beneficiary][ies] is terminated [from the date[s] specified in the following table] [from the date of IMI JU's signature] [the 45th day following the date of receipt of the request]:

<i>Full name and legal form of the participant(s) (national registration number if any)</i>	<i>End date of participation</i>

[Article 1.1][Page 1] of the GA is modified accordingly.

When the terminated participant(s) is also a beneficiary[ies]:

Article 1.5 is modified accordingly.

5.3 Change of Coordinator or Managing Entity

When the project COO or ME changes in an on-going project, it is necessary to amend the GA to modify the name of the parties (COO or ME), and Article 5.3 (bank account), Article 8 (communication details), and Annex I - DoW.

⁵ If a participant agrees to terminate its participation but omits/refuses to send to the coordinator the reports and deliverables (including Form C and CFS if appropriate), the last paragraph of article II.36.6 should apply. The amendment can be done with proof that the beneficiary has been requested (in writing) to send the reports and deliverables but failed to do so within the time-limit established by that notification. This case can be also considered as an amendment without agreement of beneficiary.

In some cases, the consortium composition remains the same (internal re-allocation of roles), but in other cases the change of COO or ME results in the termination of participation and/or addition of a new participant to the consortium.

The new COO/ME takes up the participant number of the former: COO is always participant no.1 and ME is always no.2.

When the change concerns the ME it has to make sure that any IMI funds at its disposal are returned to the consortium and put at disposal of the new ME.

The amendment request letter for a change of COO should be jointly signed by the former and the new COO. Otherwise, two separate letters having the same content should be sent from these organizations to IMI JU.

5.3.1 Coordinator/Managing Entity remains in the consortium as beneficiary

Supporting documents and actions to be completed
<ul style="list-style-type: none"> Request letter from COO or ME (COO/ME), on behalf of consortium, justifying and agreeing with the change. Letter (or two separate letters) must be signed by both former and new COO/ME's Legal representative. (if bankrupt, letter from the bankruptcy administrators)
<ul style="list-style-type: none"> Signed Administrative Forms: A2.6 for the new COO - declaration about personal data A2.7 for the new ME
<ul style="list-style-type: none"> SOFIA update, the new roles should be reflected in the participants' numbering.
<ul style="list-style-type: none"> If necessary, a new A4 form with the banking details of the new COO/ME duly signed (upload in SOFIA).
<ul style="list-style-type: none"> Upload in SOFIA a modified GA Annex I - DoW describing the work (including a revised budget breakdown, Form A3.2 from SOFIA); the modified Annex I - DoW must be dated.

5.3.2 Coordinator/Managing Entity participation terminated at its own request

In addition to the above, where participation of the former COO/ME is terminated at its own request:

Supporting documents and actions to be completed
<ul style="list-style-type: none"> In the request letter the former COO should agree on its termination, indication of specific date of termination (if bankrupt, letter from the bankruptcy administrators).
<ul style="list-style-type: none"> Form C from the leaving COO⁶ + CFS if applicable

⁶ If a participant omits/refuses to send the reports and deliverables (including form C and CFS if appropriate) to the coordinator, the last paragraph of the article II.35.6 should apply. The amendment can be done with a proof that this documentation has been requested in writing from the beneficiary but has failed to do so within the time-limit established by that notification.

- Other deliverables referred to in Art.II.4 relating to the work carried out by the COO + comments on these deliverables + declaration on distribution of payments.
- In SOFIA the termination of the COO should be indicated 'termination date' being the last day of participation in the project as it is mentioned in the request letter. Participant number 1 will be taken over by the new COO, thus the former will take the first available participant number.

5.3.3 New Coordinator/Managing Entity is not yet a participant

In addition to the above, where the new COO/ME is not yet a participant

Supporting documents and actions to be completed
<ul style="list-style-type: none"> • Form B from new COO/ME duly signed
<ul style="list-style-type: none"> • Legal/financial documents (if required)
<ul style="list-style-type: none"> • New (A4) with the banking details of the new COO/ME duly signed (upload in SOFIA).
<ul style="list-style-type: none"> • The Participant Identification Code (PIC) of the new participant, see 'Addition of participant/beneficiary'.
<ul style="list-style-type: none"> • Administrative Forms A2.1/.2/.3/.4 duly completed in SOFIA and A2.5 signed by the legal representative of the new COO/ME • In SOFIA the new COO should be added (Forms A2.1/.2/.3/.4) including the indication of the 'activation date' being the starting date of participation in the project as it is mentioned in the request letter. • Form A2.5 is signed by the legal representative of the new COO/ME • Forms A2.6 or 7 as mentioned above

Example of a request:

Change of COO

[Name of initial COO] will no longer assume the role of COO of the Project and [name of new COO] will assume this role from [date].

[This amendment request has to also include the request to modify Article 8 of the GA in order to update the COO's communication data].

Change of ME of IMI JU funding

[Name of initial ME of IMI JU funding] will no longer assume the role of ME of IMI JU funding of the Project and [name of new ME of IMI JU funding] will assume this role from [date].

[This amendment request has to also include the request to modify Article 5.3 and 8 of the GA in order to update the ME of IMI JU funding's banking details and its communication data].

5.4 Transfer of activity (leading to a transfer of rights and obligations)

5.4.1 Universal transfer of rights and obligations

Normally this situation only requires an information letter informing IMI JU of the change (see previous section 2.3)

In this case, the ‘new’ entity universally assumes all the rights and obligations of the old one, and the ‘old’ participant legally disappears. This is usually the case with takeovers, mergers, etc. The main point here is that the change in the GA is due to the disappearance of the previous beneficiary, and it affects universally all its rights and obligations, and not only those related to the GA. This is why in most cases it is not necessary to amend the GA but simply to notify IMI JU of this universal transfer of rights and obligations formally in writing. In parallel it is also necessary to inform and provide all the supporting documents to the URF/PDM in order to reflect this modification under the validated PIC number.

Examples:

Company X Ltd disappears and becomes Company X plc
Company X merges with Company Z

Nevertheless, in some cases such change within the participant may also require an amendment to the GA. For example, an amendment will be necessary for cases where the participant concerned is the COO/ME of the project and some relevant part of the GA need to be updated accordingly.

5.4.2 Partial Transfer of contractual rights and obligations

This case requires an amendment

When the original entity, despite transfer of contractual rights and obligations, continues to exist, the new legal entity (through the purchase of departments, laboratories, business units of the other entity) absorbs or takes over part of the rights and obligations of another legal entity; accordingly, some of the rights, obligations and ‘contracts’ of the previous beneficiary will be transferred (‘novated’), in favour of the new entity which became the beneficiary. This situation is considered as a ‘partial transfer’ However, the previous beneficiary continues to exist as a legal entity; so some GAs may be affected because only part of its rights and obligations are transferred to the new one.

Example: Company X sells its mobile phone division to Company Z; all GAs where the mobile phone division of X was involved will be affected by a transfer of rights and obligations to company Z; other GAs where other divisions of company X work will not be affected.

Additionally, some specific cases where the original entity disappears may still be considered as ‘partial transfer’: unlike the first case, even if the original beneficiary disappears, there is not a universal transfer to a new single entity, but partial transfers to different ones.

Example: Company X is bought by two other companies (Y & Z), one of which will absorb the mobile phone division and the other the remaining divisions. Here for some GAs there will be a transfer of rights and obligations from X to Y, for some others from X to Z. In these cases of partial transfer, for reasons of legal certainty and attribution of liabilities, a formal amendment of each GA concerned is required.

Supporting documents and actions to be completed

- Letter from the COO, on behalf of consortium, with the request and agreement for an amendment, explaining the context and the nature of the change

<ul style="list-style-type: none"> • Form B from the new participant duly signed. The starting date of participation is the date when the transfer of rights and obligations occurred.
<ul style="list-style-type: none"> • Administrative Forms A2.1/.2/.3/.4 duly completed in SOFIA and A2.5 signed by the legal representative of the new participant.
<ul style="list-style-type: none"> • Legal documents supporting and justifying the transfer of rights & obligations; financial reports, if required.
<ul style="list-style-type: none"> • The Participant Identification Code (PIC) for any new legal entity.

Example of request:

[Full name and legal form of the beneficiary which takes over the rights and obligations] established in [full address/city/state/province/country], represented by [name of legal representative & function] and/or [name of legal representative & function], or [her/his/their authorised representative], for the purposes of this GA has taken over the rights and obligations of [initial beneficiary's name and legal form], as of [insert date].

Any reference in the grant agreement, including Annex I and the table of the estimated breakdown of costs, to [initial beneficiary's name and legal form] shall be deemed to be a reference to [name and legal form of the beneficiary which takes over the rights and obligations], therefore [name and legal form of the beneficiary which takes over the rights and obligations] is a member of the consortium identified in Article 1.1.

Notwithstanding the transfer referred to above, IMI JU and/or the European Court of Auditors and their authorised representatives shall continue to enjoy the rights referred to in Articles 22 and 23 of Annex II to the GA in respect of work undertaken by [initial beneficiary's name and legal form] which shall continue to be bound by the provisions of the GA and its Annexes relevant to the effective exercise of these rights.

5.5 Termination following non-accession to the Grant Agreement (Form A not received)

When one or more participant/beneficiary listed under Article 1.1 of the GA has not acceded to the GA - by signing the Annex III - Form A, it must be removed from the GA.

Supporting documents and actions to be completed
<ul style="list-style-type: none"> • Letter from COO, on behalf of consortium, justifying the non-accession, impact on the project and related mitigation plan, if necessary.
<ul style="list-style-type: none"> • Upload in SOFIA a modified GA Annex I - DoW describing the work (including a revised budget breakdown, Form A3.2 from SOFIA); the modified Annex I - DoW must be dated.
<ul style="list-style-type: none"> • May be linked with addition of new participant(s)/beneficiary(ies) and Modification of Annex I - DoW, see 'addition of participant/beneficiary'.

Example of request:

Removal of one or more legal entities from the list in Article 1.1 due to their non-accession to the GA

The following entit[y][ies] [is][are] removed from the list in Article 1.1 due to [its] [their] non-accession to the GA:

- [insert full name and legal form of the participant(s)] & [national registration number (if any)]

6. Type of other changes

6.1 Modification of Annex I -Description of work

The modification of the Annex I - DoW may be part of another amendment (e.g. change of consortium composition) or stands by itself for any modification occurring in the way the projects and related activities are developing (e.g. including the addition/removal of subcontracting). Normally it concerns the following aspects:

- *Changes in the work to be performed:* an amendment is required for removal/addition/modification of tasks including work-packages, milestones and deliverables, described in the Annex I - DoW, or for substantial changes in the distribution of the work between participants. The latter also applies in case of changes in the consortium composition to reflect the new allocation of work.
- *Changes in the estimative budget breakdown:* in this case an amendment is only required for the cases of addition and termination of participants and also for substantial changes linked to the above-mentioned changes in the work.

In the case of budget transfers, Article 5 of the GA allows beneficiaries to transfer budget between different activities and between them in so far as the work is carried out as foreseen in Annex I - DoW. An amendment to the GA will be necessary in all cases if the budget transfer arises from a significant change that affects the technical work as foreseen in Annex I - DoW, including the subcontracting of a task that was initially meant to be carried out by a beneficiary. In case of doubt consultation with the scientific officer responsible at IMI JU is recommended.

- *The introduction/ modification of subcontractors, third parties or the inclusion of a direct financial contribution from an EFPIA company to a beneficiary⁷.*

Supporting documents and actions to be completed
<ul style="list-style-type: none"> • Letter from COO, on behalf of consortium, justifying and agreeing the changes in the new Annex I – DoW.
<ul style="list-style-type: none"> • Upload a modified Annex I - DoW in SOFIA describing the work (including a revised budget breakdown, A3.2 Form from SOFIA); the modified Annex I - DoW must be dated.

⁷ The direct financial contributions from EFPIA participants to beneficiaries must be mentioned in Annex I.

Where this is not foreseen it needs to be added by means of an amendment request indicating:

- the EFPIA partner making the direct financial contribution;
- the beneficiary receiving it;
- the work package and tasks for which the contribution is made.

- In the case of subcontracting a justification for the activity and an estimation of the tasks should be provided in Annex I - DoW.
- For subcontracting outside EU or Associated Countries (AC), exceptional circumstances (scientific/technical) need to be justified for IMI JU approval
- For the introduction of third parties under Special Clause 4 (carrying out part of the work), the PIC code of the entity has to be provided and relevant information included in SOFIA under the linked beneficiary. The new legal entity must self-register in PDM-URF and provide legal and financial documents + administrative forms, before the amendment is submitted.

Example of request:

Annex I - DoW is modified.

The revised Annex I dated [DATE] attached to your request replaces any former version.

[The revised page[s] numbered '[' [through '['] dated [insert date] attached to this letter shall replace the corresponding page[s] in Annex I to the GA.]

[Addendum No.] dated [insert date] attached to this letter shall be incorporated as part of Annex I to the GA. In case of conflict between Annex I and any provisions of Addendum No.[] the latter shall prevail.]

6.1.1 Introduction/Modification of Work-packages/ Deliverables/ Milestones Lists

General

The SOFIA IT Tool allows encoding under relevant sections (see images below) project work-packages, milestones and deliverables. This project related information can be introduced or modified, in accordance with the Annex I – DoW, during any open amendment session.

Work Package List

ADD NEW WORK-PACKAGE FOR PROJECT PROPOSAL:

Work plan						
Work-packages List						
WP No	Title	Type of Activity	Lead part. No	Person-months	Start month	End month
						Add New Work-package
Deliverables List						
Nature						
Final Del. No.*	Deliverable title	Nature	Other	Delivery date		
						Add New Deliverable
* Numbering of deliverables and milestones is indicative only, based on the current DOW. Subject to revision at the time of integration with the current workplan.						
Milestones List						
Milestone No.	Milestone title	WP involved	Delivery date	Means of verification		Add New Milestone

Please make sure encoding all relevant information as requested by the SOFIA IT Tool in

accordance with what is described in the relevant Annex I – DoW.

Deliverables List

ADD NEW DELIVERABLE FOR PROJECT:

WP No.:	<input type="text" value="Select WP No"/>
Deliverable No:	<input type="text"/>
Deliverable:	D
Deliverable Title:	<input type="text"/>
	(120 characters remaining)
Nature:	<input type="radio"/> Report (R) <input type="radio"/> Prototype (P) <input type="radio"/> Other (O) <input type="text"/>
	(120 characters remaining)
Delivery date (in months):	<input type="text"/>

Please make sure encoding all relevant information as requested by the SOFIA IT Tool in accordance with what is described in the relevant Annex I – DoW.

Milestones List

ADD NEW MILESTONE FOR PROJECT:

Milestone No:	<input type="text"/>
Milestone Title:	<input type="text"/>
	(120 characters remaining)
WP involved:	<input type="text" value="Select WP No"/>
Delivery date (in months):	<input type="text"/>
Means of verification:	<input type="text"/>

Please make sure encoding all relevant information as requested by the SOFIA IT Tool in accordance with what is described in the relevant Annex I – DoW.

6.2 Change of Managing Entity banking details

The modification of the ME’s banking details which are mentioned in the GA (Article 5.3) has to be done by means of an amendment. The change of name and/or legal details may imply the modification of its banking details.

Supporting documents and actions to be completed
<ul style="list-style-type: none"> • Letter from COO on behalf of consortium requesting the change of bank account in the GA, Article 5.3.
<ul style="list-style-type: none"> • Updated A4 banking details form duly signed (uploaded in SOFIA).

Example of request:

The ME's banking details as indicated in Article 5.3 of the GA are amended as follows:

Name of account holder: Name of bank:

Account reference: [IBAN/sort code and number]

6.3 Change of the contact details of IMI JU, COO or ME (Art. 8 of GA)

The details included in Article 8 are those required for the communication between IMI and the COO and the ME. Should the COO or IMI change its contact name and/or the address mentioned in that Article, the GA has to be updated accordingly by means of an amendment. This Article will always have to be modified in case of changes of the COO and the ME. Also when the name of the participant changes, the 'name of the bank account holder' mentioned in the GA, probably needs to change as well, and has to be updated accordingly by means of an amendment.

Supporting documents and actions to be completed
<ul style="list-style-type: none"> • Letter from COO, on behalf of consortium, justifying and requesting change
<ul style="list-style-type: none"> • In case of change of legal details, the related supporting documents will be necessary. The changes have to be introduced via the PDM/Unique Registration Facility: (http://ec.europa.eu/research/participants/urf).
<ul style="list-style-type: none"> • Updated relevant administrative forms in SOFIA.

Example of request:

Change of [COO] [ME of IMI JU funding]'s [name] [and] [address(es)]

[The [name] [and] [address(es)] specified in Article 8.1 of the GA is modified as follows:

For the [coordinator] [Managing Entity of IMI JU funding]: [name of contact person] [contact address]]

[The address specified in Article 8.2 of the grant agreement is modified as follows:

For the coordinator:]

6.4 Modification of the project duration and /or start date

As the duration of the project (number of months), and its starting date are mentioned in the GA, any modification has to be done through an amendment. In principle, the modification of the duration of the project should be requested before the end of the project. The consortium has to be aware that even if the duration of the project is extended it will have to finalise the work with the same maximum amount of IMI contribution.

The extension implies a longer duration of the project. Thus the submission and approval of the final report will be postponed along with the final payment. This may have a financial impact on beneficiaries waiting for the payment of the balance (i.e. final payment)⁸.

Where the requested extension is longer than 6 months⁹, prior to the submission of the formal amendment request, the consortium should obtain a specific approval from IMI JU by submitting a detailed justification to the IMI Executive Director.

Supporting documents and actions to be completed	
	<ul style="list-style-type: none"> Letter from COO on behalf of consortium, justifying and agreeing on prolongation and/or change.
If applicable	<ul style="list-style-type: none"> Upload in SOFIA a modified Annex I - DoW describing the work (including a revised budget breakdown, Form A3.2 from SOFIA); the modified Annex I - DoW must be dated. The requested modification of reporting periods should be indicated in the letter and in SOFIA – Form A5 (reporting periods).

Example of request:

- New starting date of the project*

The start date of the project specified in Article 3 of the grant agreement is modified as follows:

New starting date of the project: [insert new start date]

- New duration including extension*

Article 3 - — Duration and start date of the project

The duration of the project shall be XX months from DD/MM/YY (hereinafter referred to as the 'start date').

6.5 Modification of the reporting periods

The project is divided into reporting periods of a specific duration, which are determined in Article 4 of the GA. The modification of the number and/or duration of the reporting periods

⁸ According to the IMI Model Grant Agreement Article II.6.2:

The total amount of the pre-financing and interim payments shall not exceed 90% of the maximum IMI JU financial contribution defined in Article 5.1.

⁹ IMI JU does not accept extension of a project longer than 12 months.

has to be done by way of an amendment to the GA.

This type of modification may be linked to an amendment for 'Modification of duration' (see above 6.5)

Supporting documents and actions to be completed
<ul style="list-style-type: none"> • Letter from COO, on behalf of the consortium, justifying and agreeing modification and modified (Form A5).
<ul style="list-style-type: none"> • Updated Annex I - DoW (including revised breakdown of costs if necessary).

Example of request:

Article 4 of the grant agreement is modified as follows:

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

6.6 Modification of IMI JU financial contribution

The modification of the maximum financial contribution to the project indicated in the GA has to be made through an amendment to the GA.

The modification of the maximum financial contribution may lead to a change in the pre-financing and to a change of Annex I - DoW.

Supporting documents and actions to be completed
<ul style="list-style-type: none"> • New IMI GB decision, in the case of an increase in contribution and additional commitment.
<ul style="list-style-type: none"> • Letter from COO, on behalf of consortium, justifying and requesting change.
<ul style="list-style-type: none"> • Updated Annex I - DoW (including revised breakdown of costs, Form A3.2).
<ul style="list-style-type: none"> • Updated relevant administrative forms (A3.1/2, A5) in SOFIA. • If applicable, change in pre-financing (Article 6).
<ul style="list-style-type: none"> • If change refers to a reduction of IMI contribution, de-commitment has to be made.

Example of request:

[The financial contribution of IMI JU is [increased][decreased] by EUR [insert increased/decreased amount] ([insert amount in words] EUROS).]

The maximum financial contribution of IMI JU specified in Article 5.1 of the grant agreement is modified as follows:

EUR [insert new amount] ([insert amount in words] EUROS)

This modification takes effect from [insert date] [date of entry into force of this amendment].

6.7 Addition /removal or modification of special clauses

Some standard special clauses are part of the IMI model GA. These special clauses establish special conditions to adapt the GA to specific activities and/or needs of some participants and/or consortia. They take precedence over any other provisions of the GA (including its Annexes). Their inclusion under Article 7 of the GA needs to be specifically agreed between the consortium and IMI JU.

Any addition, removal or modification of a special clause has to be done through an amendment to the GA.

The text of these special clauses has been approved by IMI JU and cannot be modified. However, in particular cases it may be necessary to complete some of the options available.

To see the list of all special clauses applicable to the IMI JU model GA - ANNEX VII - click [here](#).

Supporting documents and actions to be completed	
<ul style="list-style-type: none"> • Letter from COO, on behalf of consortium, justifying and requesting addition or removal of the special clause. • Attention: depending on the type of clause, it may be necessary to provide additional information, legal documents, administrative forms, budget breakdown, modified Annex I - DoW, etc. 	

Example of request:

Addition

The special clause(s)

No.	<i>Text of the special clause</i>

[is] [are] added to Article 7 of the grant agreement as from [insert date].

OR

Removal

The special clause(s)

No.	<i>Text of the special clause</i>

[is] [are] removed from Article 7 of the grant agreement as from [insert date].

OR

Modification

The special clause(s) set out in Article 7 of the grant agreement [is] [are] modified as follows:

No	Text of the special clause

as from [insert date].

6.8 A beneficiary becomes or enters under the control of an EFPIA company

It may occur that an organisation which was originally a beneficiary of IMI project, during the project implementation, becomes or enters under the control of a research based pharmaceutical company member of EFPIA.¹⁰

Consequently an amendment is necessary in order to reflect this situation in the GA. As of the date of changing the control:

- such organisation is cannot be a beneficiary anymore (i.e. it shall be removed from article 1.5), ;
- it is not anymore eligible for IMI JU funding, hence all costs incurred will count as EFPIA in-kind contribution from the date of change in control .

Supporting documents and actions to be completed
<ul style="list-style-type: none"> • Letter from COO, on behalf of consortium, justifying the request and explaining if this has an impact on the internal allocation of tasks. • The change of status (from beneficiary to EFPIA company) should be reflected in SOFIA. • Attention: the COO and the participant should be considered if PDM/URF needs to be informed about the change of control.

7. IMI initiated amendments

7.1 Non EU in kind

This type of amendment is required when the IMI Governing Board, following a formal request from EFPIA, accepts¹¹ that a fraction of the total eligible EFPIA in-kind contribution is incurred outside the EU Member States and FP7 Associated Countries (AC). Such a fraction is to be considered as part of the total eligible EFPIA in-kind contribution.

¹⁰ This is a different situation to one where an organization which is eligible to receive IMI funding changes its status during the life of the project. In so much as the change of status is not due to its falling under the control of an EFPIA company, the organization remains eligible to receive IMI funding.

¹¹ In derogation to point (g) of Article II.13.1 and without prejudice to the other cost eligibility conditions set out in the GA.

The Grant Agreement has to be amended in order to include the special clause 13 (a or b) together with the indication, in its Annex I - DoW, of the main elements about the non-EU EFPIA in-kind contribution (i.e. type of activities, EFPIA participants concerned, budget per EFPIA company concerned).

Three copies of the draft amendment, prepared and sent by IMI JU to the consortium for signature, has to be signed by the legal representatives of both the COO and ME, likewise the original GA.

Together with the signature of the amendment, the consortium has to update the Annex I - DoW. Generally, the consortium has a choice between the following options:

- to directly modify the relevant sections of the Annex I - DoW, or
- to incorporate an Addendum (No.X – dated with all relevant information) to the existing Annex I – DoW.

Please note that all relevant modifications (budget, participants data etc.) need also to be encoded in SOFIA where the modified Annex I - DoW or Addendum No.X (together with the last approved DoW) needs to be uploaded.

In SOFIA it is also possible to indicate the amount of eligible non-EU in-kind contribution, reflecting the amount indicated in the special clause 13 (a), and the ineligible additional amount not covered by a special clause)

The maximum total amount of eligible non-EU shall reflect the amount accepted by the IMI JU Governing Board and which is indicated in the special clause 13 (a) . This amount is fully eligible as far as it represents 10% of the total eligible in-kind contribution. The non-EU in-kind contribution may be eligible with retroactive effect from the starting date of the ongoing reporting period at the date of the IMI Governing Board decision accepting such contributions.

Supporting documents and actions to be completed

- Three original Amendments signed by the legal representatives of both the COO and ME
- Update of the relevant sections of Annex I – DoW (including revised breakdown of costs, Form A3.2), or incorporate an Addendum (No.X)
- Update SOFIA budget tables Form A3.1/2

7.2 ENSO amendment

This type of amendment takes place when a proposal from an existing IMI consortium is selected following an ENSO Call for proposals (<http://www.imi.europa.eu/content/new-opportunities>). The selected ENSO proposals enter into negotiation with IMI JU in order to amend the original GA by integrating the ENSO activities. To finalise the negotiation phase, the SOFIA tool needs to be updated under the new amendment session in any of its relevant sections (such as participants, budget, duration, work-packages, milestones, deliverables, etc) and with an amended DoW integrating the new ENSO activities. Once this is done and accepted by IMI JU, the draft amendment will be sent to the consortium for signature. Three copies of the amendment will have to be signed by the legal representatives of both the COO and ME, likewise the original GA.

An ENSO amendment may imply the need for other modifications – see Section 7.2.1.

7.2.1 Modification of IMI JU Financial contribution and Annex I – DoW

See also section 6.6

Supporting documents and actions to be completed
<ul style="list-style-type: none"> • Updated relevant administrative forms (A3.1/2, A5) in SOFIA. The total amount of IMI and in-kind contribution should reflect what was agreed at the end of the negotiation phase for the ENSO proposal. • Updated Annex I - DoW (including revised breakdown of costs - Form A3.2) If starting date of ENSO activities prior to signature of ENSO amendment, a sound justification should be provided to IMI JU for approval • If applicable, change in pre-financing (GA, Article 6)

7.2.2 Addition of participant(s)/beneficiary (ies), if applicable

See section 5.1

7.2.3 Modification of the duration, if applicable

See section 6.4

8. Definitions

COO – IMI Project Coordinator

DoW - Annex I – Description of Work

ED – IMI Executive Director

EFPIA - European Federation of Pharmaceutical Industries and Associations

ENSO - IMI Call for proposals to explore new scientific opportunities

GA - Grant Agreement

IMI JU - Innovative Medicine Initiative Joint Undertaking

LEAR - Legal entity appointed representative

ME - Managing Entity

SO – IMI Scientific Officer

SOFIA - Submission OF Information Application

URF/PDM - Unique Registration Facility/ Participant Data Management