



Amendments Guide for IMI2 Grant Agreements

This guide applies to Grant Agreements signed for projects selected under Call 1-23 of IMI2 JU, launched between 2014 and 2020.

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List of acronyms

AP	Associated Partner
BNRF	Beneficiary not receiving funding
BRF	Beneficiary receiving funding
COO	Project Coordinator
DoA	Description of Action
DoH	Declaration of Honour
EFPIA	The European Federation of Pharmaceutical Industries and Associations
FC	Financial Contribution
FO	Financial Officer
GA	Grant Agreement
IHI JU	Innovative Health Initiative Joint Undertaking
IMI2 JU	Innovative Medicines Initiative Joint Undertaking
JSL	Joint and Several Liability
LEAR	Legal Entity Appointed Representative
LO	Legal Officer
LTP	Linked Third Party
MGA	Model Grant Agreement
PIC	Participant Identification Code
PLSIGN	Project Legal Signatory
PM	Person Month
PT	Partial Takeover
SME	Small and medium-sized enterprise
SO	Scientific Officer
WP	Work Package

Introduction

The purpose of this document is to provide practical guidance to the coordinators (COO) of IMI2 projects on how to amend their Grant Agreement (GA) signed with the Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU).

This guide complements the [H2020 online manual on the Amendments to the Grant Agreement](#), which, in addition to the IMI2 Annotated Model Grant Agreement ('IMI2 AGA'), is the main source of information while preparing an amendment request. Additional guidance on how to encode (step-by-step) the amendment in the portal is available on the portal's IT wiki ([How to prepare an amendment](#) and [Available types for consortium-requested amendments](#)).

The document describes the most frequent amendment types that require special attention regarding IMI2's specificities, such as the addition/removal of Beneficiaries Not Receiving JU funding (BNRF), which are often EFPIA companies or Associated Partners (AP); a change in the non-EU in-kind contribution; changes in financial contributions, etc. Other "frequent" modifications, such as changes of bank account; the addition/removal of international partners; changes involving beneficiaries & linked third parties in relation to the legal link; and joint & several liability can be found in the [H2020 online manual on the Amendments to the Grant Agreement](#).

This guide provides examples of wording and some tips on how to prepare an amendment with a particular focus on the following documents:

- Amendment request letter
- Description of Action (DoA - Annex 1 Part A and Part B), including history of changes
- Annex 2 (estimated budget).

This guide applies **only** to IMI2 Grant Agreements¹.

¹ For IMI1 Grant Agreements, please refer to the relevant guidance here.

The amendment process in a nutshell

Before submitting any amendment request, the project coordinator is advised to contact the IHI scientific officer (SO) in charge of the project, outlining the main elements/reasons for the planned amendment.

To start the amendment process, the consortium (coordinator and other beneficiaries) should launch the amendment and encode changes to the GA Data in the Funding and Tenders Portal (*e.g. duration, removal/addition of beneficiaries, change of coordinator, etc*) together with a sound justification for all modifications made. Some amendment types require supporting documents, (for instance when adding a Linked Third Party (LTP)).

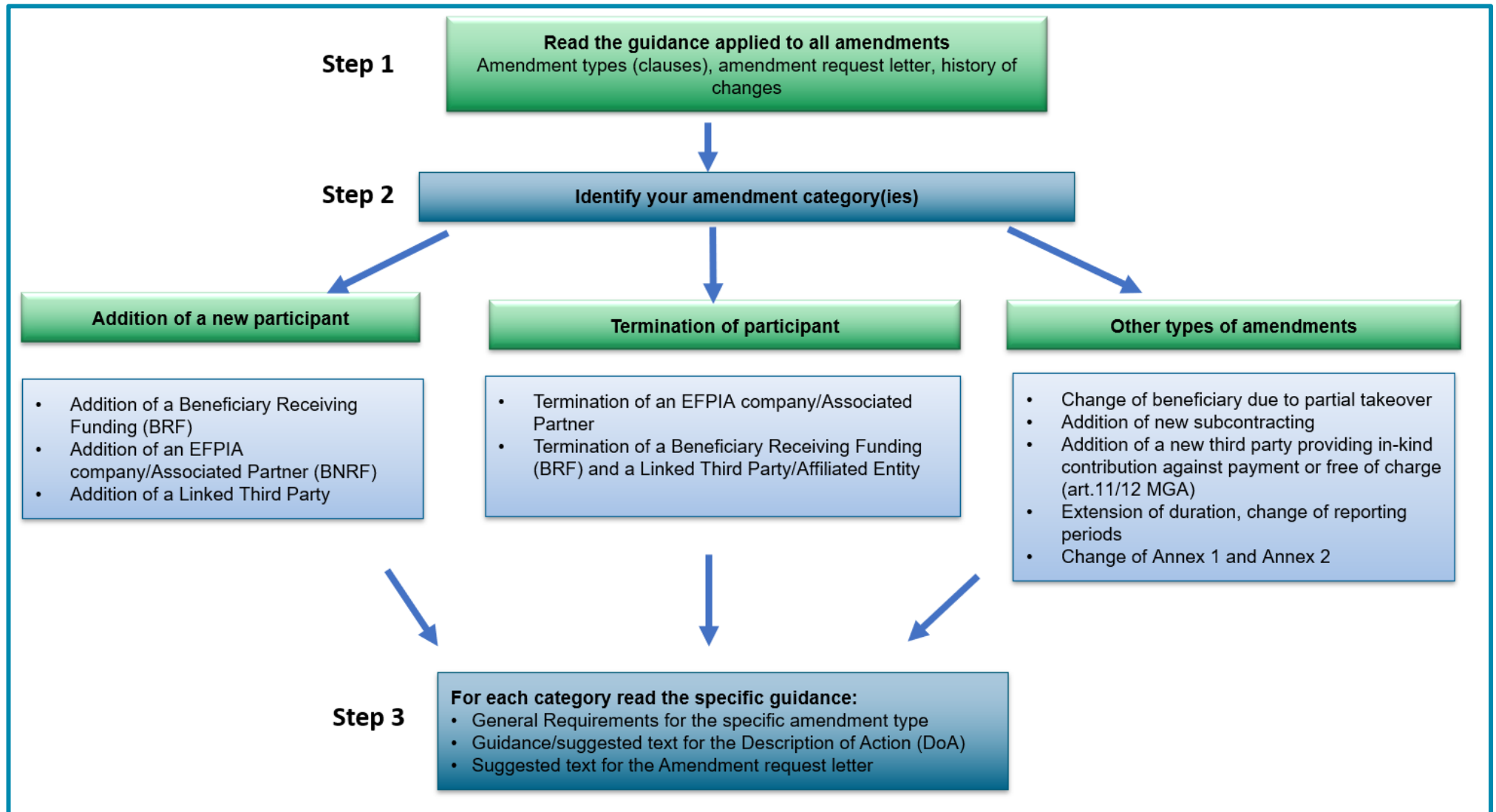
When the consortium has finished preparing the draft amendment request, the draft is sent via the Funding and Tenders Portal to the scientific, financial and legal officers in charge of the project for review.

After the officers have assessed the amendment request, the SO can send back the amendment for revision, or validate the draft amendment request in the tool.

Once the amendment has been validated by the SO, the coordinator can formally submit it on behalf of the consortium. To do so, the PLSIGN of the coordinator signs and submits the Amendment Request and the Amendment (first signature; electronic). From this point on, any corrections to the grant amendment data will result in the amendment being automatically sent back to the SO for review. Therefore, it is of paramount importance that all data are carefully quality checked before pressing the “submit” button as after this the data are “locked” and cannot be modified in any way.

All important communications between the coordinator and the IHI JU must be done using the Communication centre in the Funding and Tenders Portal.

How to navigate the guidance document



1 Guidance for all types of amendments

The following section provides guidance on the type of amendment clauses to select, the principles to follow while preparing the amendment request letter, and specific instructions on how to keep track of the history of changes.

1.1 Amendment types (clauses)

Depending on the changes needed in the grant data (e.g. termination of a beneficiary, addition of a new beneficiary, a new subcontract, extension, etc.), different amendment types and clauses are available in the portal. Amendment clauses can be grouped into three categories: *automatic*, those *selected by the EU / IHI*, and *'on demand'*. Annex 1 of this document lists the clauses under each category, and the steps to be taken for each category are described below.

- **Automatic:** Manual selection of the automatic clauses **is not needed!** Clauses are automatically selected by modifying the relevant data in the Grant Agreement data tabs.
- **Selected by the EU (IHI JU Programme Office):** Contact your scientific officer (SO) to enable the specific clause(s).

To select/unselect a manual Grant Agreement option or a manual amendment type (e.g. change of Annex 1 and change of Annex 2), you have to ask the IHI SO. The SO can make these changes while your session is open.

If you would like to change **only** Annex 1 - Description of Action (part B), you must ask the SO to first select the manual type 'Change of Annex 1'. Only then will the document Annex 1 - Description of Action (part B) and the Upload button appear in the list of documents.

- **On demand:** Contact your IHI SO to enable the specific clause.

It is very important to submit the amendment prior to the project end date.

In **exceptional cases** – e.g. if the bank account changes, or the coordinator responsible for paying the balance is replaced, the amendment can be introduced after the end date of the project, but before the final payment.

1.2 Amendment request letter

The information relating to the amendment justification introduced in the portal is used to automatically generate the request letter. Therefore, your approach needs to be formal and structured.

The request letter should include:

- all changes concisely justified following the order and the structure of the amendment clauses selected;
- brief descriptions of the main change(s), ensuring that the information included in the amendment request letter is consistent with the encoded modification(s) in the Grant Agreement data, i.e. the text of the amendment letter vs Annex 1 Part A & Part B, Annex 2 (*see sections “Changes of Annex 1” and “Changes of Annex 2” for further guidance*), and is reflected properly in the history of changes.
- a confirmation that the changes proposed do not depart from the original project objectives.

1.3 History of changes

With each amendment, the DoA- History of Changes section should be updated accordingly.

When you launch an amendment request in the Grant Management Service online tool, the amendment is automatically assigned a reference number, e.g. AMD-project number – XX. Please use this amendment number to identify the changes made in the new amendment. To avoid confusion, **do not use dates or version numbers**.

Major changes should be briefly listed with reference to the related section(s) as described in the examples below. The detailed justification will be included in the request letter. Please remember that the history of changes should include a list of all changes, both in Part A (encoded in the portal) and Part B (the pdf) of the Description of the Action (Annex 1). Please avoid including figures that could lead to manual mistakes and inconsistencies.

Suggested text for the DoA - History of Changes

Amendment reference number (e.g. AMD-project number – XX):
e.g. partner number X and name: addition of subcontracting costs in Annex 2 and in section 4.2.
e.g. addition of new partner number X and name: update of relevant sections Annex 1 Part A (list of beneficiaries, WPs, PM,) and Part B (section 4.1) and Annex 2.

2 Guidance per amendment category


2.1 Addition of a new participant

In justified cases, the consortium may request to add a new participant. This new participant can be:

- a Beneficiary Receiving funding (BRF);
- a Beneficiary not receiving funding (BNRF), such as an EFPIA company, an Associated Partner (AP), or other;
- a Linked Third Party (displayed in SYGMA as Affiliated entities).

Any new beneficiary receiving funding from IHI JU and/or via a financial contribution from EFPIA or an Associated Partner must comply with the eligibility criteria of the work plan/Call and with the non-exclusion criteria.

New participants (BNRF and/or BRF) must commit to implement the action under the same terms and conditions as the other beneficiaries. All new participants must have sufficient operational and financial capacity.

For all additions	General requirements and guidance/suggested text for the Description of Action (DoA)	Suggested text Amendment request letter
<p>The following annexes should be modified accordingly</p> <ul style="list-style-type: none"> ▪ Annex 1 (DoA) ▪ Annex 2 (Budget Table) <p>The Amendment request letter should specify</p> <ul style="list-style-type: none"> ▪ justification for the need to add a new beneficiary/LTP ▪ justification should be provided for a retroactive start date ▪ the operational capacity justification ▪ briefly describe the changes in Annex 1 (new tasks / reallocation of tasks and changes to the use of resources – please do not include details on figures/PMs as these are included in Annex 1 Part A) ▪ Annex 2 reflects the budget allocated to the new participant/LTP (when relevant) and (if applicable) any redistribution of budget. <p> If necessary, Annex 2a: Unit cost for SME owners/natural beneficiaries without salary (see template)</p>	<ol style="list-style-type: none"> 1. The new participant must register in the Participant Register and be validated — unless they already have a validated participant identification code (PIC) <ul style="list-style-type: none"> ▪ Every beneficiary and linked third party must be validated in the Participant Register ▪ Once validated, a LEAR must be appointed for each beneficiary and linked third party ▪ Project roles must be appointed for all beneficiaries and linked third parties, and in particular the Project Legal Signatory (PLSIGN) 2. The new participant must sign the Declaration of Honour ('DoH') & Accession Form (Annex 3) in the electronic exchange system. 3. Annex 1 (DoA) should be updated as follows: <ul style="list-style-type: none"> ▪ Part A: relevant WPs and tasks, deliverables, effort as PMs ▪ Part B (PDF): <ul style="list-style-type: none"> ✓ Section 3.4 Resources to be committed ✓ 4.1 Participants ✓ 4.2 Third parties (as relevant) ✓ Gantt chart (if relevant) ✓ Management structures and governance (if applicable) 4. Annex 2 should be updated (including Annex 2a, if necessary). Redistribution of funds should be appropriately reflected in the financial information tab in the Portal. 	<p><i>“Short name of new beneficiary” is joining the consortium on the date specified in the Annex 1 Part A due to the (include a reason e.g. 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 consortium; one withdrawing participant needs to be replaced, or other).</i></p> <p><i>“Short name of new beneficiary” and “include brief narrative of main task in WPs”.</i></p> <p><i>The new participant has the operational capacity to carry out the proposed work because “include justification on operational capacity (e.g. in terms of expertise, infrastructure, data, etc.)”.</i></p> <p>Note: <i>Retroactive starting date</i> is exceptionally allowed, if dully justified</p>

	<p>5. For each partner, please ensure the correct box is ticked (in Beneficiaries - Partner Summary) where relevant:</p> <ul style="list-style-type: none"> ▪ SME & turnover up to EUR 500 million ▪ EFPIA member ▪ IMI2 Associated Partner (if a new entity would like to participate as an Associated Partner, please contact your Scientific Officer asap and well in advance of the amendment submission) ▪ Regulatory Agency ▪ Patient Organisation 	
2.1.1 Addition of a Beneficiary Receiving Funding (BRF)		
<p><i>Please follow the instructions for all additions indicated in the table at the beginning of this section.</i></p> <p>Additional requirements:</p> <ul style="list-style-type: none"> ▪ If the new Beneficiary is an SME, the SME self-assessment questionnaire in the Funding & tenders portal should be filled in. This involves submitting their headcount and financial data (latest closed annual accounts) in the validation interface of the Funding & Tenders Portal. See the following link: http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applying-for-funding/register-an-organisation/registration-of-organisation_en.htm#sme ▪ Based on the criteria above, private for profit companies with an annual turnover up to EUR 500 million do not qualify as SMEs; yet they may still be eligible for funding² under certain 	<p><i>Please follow the general requirements for all additions indicated in the table at the beginning of this section.</i></p>	<p><i>Please follow the suggested text for all additions indicated in the table at the beginning of this section.</i></p> <p>Additional requirements:</p> <p>Note: if the budget has been reallocated or combined with Financial Contribution (FC), please specify the redistribution.</p>

² Article 1 of the Commission Delegated Regulation No 622/2014 of 14 February 2014: '[...] other companies with an annual turnover of EUR 500 million or less, the latter not being affiliated entities of companies with an annual turnover of more than 500 million; the definition of 'affiliated entities'³ within the meaning of Article 2(1)(2) of Regulation (EU) No 1290/2013 shall apply mutatis mutandis'.

conditions. Consequently, they need to fill in a **dedicated checklist** provided by the IHI JU office and upload it as a document in the Funding & Tenders Portal.

2.1.2 Addition of an EFPIA company/Associated Partner (BNRF)/Other

Please follow the instructions for all additions indicated in the table at the beginning of this section.

Additional requirements:

- The Amendment request letter should explain how the total in-kind contribution, the non-EU in-kind contribution and the financial contribution(s), if applicable, are reflected in Annex 2 (please do not include details on figures as these are included in Annex 1 Part B section 3.4 – please provide the total amount).
- The Amendment request letter should include a confirmation that the EFPIA office has been informed of the changes in the EFPIA contributions (EU and non-EU in kind and/or financial contributions) to the project.
- If an Associated Partner (AP) is being added that AP should submit an application letter to the IHI Governing Board setting out their own credentials and details of their contribution to both the specific topic/project and to the larger strategic goals of the IMI2 programme. In order to receive the templates for this application letter, please contact IHI JU Programme Office.

For ‘Other’, the ‘additional requirements’ above should not apply, but information should

Please follow the general requirements for all additions, indicated in the table at the beginning of this section.

Additional requirements:

Annex 1 (DoA) should be updated if relevant:

Table 3.4c - Financial Contributions (FC) and their justification (from who to whom, the amount and for which tasks, WP).

FC provided	FC received	Amount (€)	Related activities
BNRF Number/Short Name	Participant Y	Total	e.g. concerned task, activities, WPs

Note: the beneficiary receiving the financial contribution must include the corresponding costs in its total costs in the budget table in the portal.

Table 3.4d - Non-EU in kind (amount and justification)

Participant	Non-EU activities and justification
BNRF Number/Short Name	e.g. concerned task, activities, WPs Justification

Section 3.4e - Scientifically relevant activities of EFPIA and IMI2 Associated Partners for generating data / collecting samples in prospective activities

Please follow suggested text for all additions, indicated in the table at the beginning of this section.

Additional requirements:

EFPIA company/Associated Partner X will provide the total contribution of (amount) composed of:

- EU in-kind contribution (if applicable)
- non-EU in-kind contribution (if applicable)
- financial contribution (if applicable) reflected in Annex 1 Part B section 3.4 and financial information in the portal.
- The EFPIA office has been informed on “include date” of the increase in the of EU in-kind contribution (if applicable) / non-EU in-kind contribution (if applicable) / financial contribution (if applicable)

be included on the nature of the ‘Other’s’ contribution.

This is for scientifically relevant activities generating data in prospective activities during the funded action that are part of broader industry clinical studies but are related to the objectives of the project, for example, bringing a specific set of data, using a specific section of a study. These activities and related budget should be clearly described and justified in order to be counted as in-kind contribution.

<i>Participant</i>	<i>Cost (€)</i>	<i>Description of samples/data rationale for inclusion e.g. to activities, WPs</i>
<i>BNRF Number/Short Name</i>	<i>Total</i>	

Note: For prospective studies, the annex of clinical studies should be used to provide minimum key information on the study(ies) and incorporated as an annex to the DoA part B.

For ‘Other’ – Annex I and Annex II should be updated to reflect the nature of the contribution, tasks assigned etc.

2.1.3 Addition of a Linked Third Party

Please follow the instructions for all additions indicated in the table at the beginning of this section.

Additional requirements:

- A legal document indicating the link between the linked third party and the main beneficiary (statutes, extracts from national companies’ registration registers, financial data, agreement, decree, citation of the applicable rules with hyperlinks to the texts, etc) should be sent to IHI via normal Communication in the portal.
- If the linked third party (LTP) receives more than 50% of the main BRF funding, a joint and

Please follow the general requirements for all additions indicated in the table at the beginning of this section.

Additional requirements:

Suggested text for the DoA, section 4.2:

Beneficiary X

Does the participant envisage that part of its work is performed by linked third parties? YES

The LTP or Affiliated Entity X will perform the following activities X,Y,Z....related to tasks X and Y of WPX and with a budget of EUR xxx.

Please follow suggested text for all additions indicated in the table at the beginning of this section.

Additional requirements:

Besides the elements to include for all additions (point 2.1), please include a sentence confirming that the proof of the legal link and the joint and several liability (if applicable) have been submitted.

“Short name of the beneficiary” requests to include the Linked Third Party (LTP) “Name of new linked third party” on the date specified in the Annex

<p>several liability ('JSL') should apply. Where requested by the IHI JU and if applicable, a joint and several liability declaration (see ANNEX 3a of the IMI2 Model Grant Agreement) should be signed and sent to IHI via normal Communication in the portal.</p> <ul style="list-style-type: none"> ▪ Attention: Affiliates of participating EFPIA companies and/or IMI2 Associated Partners are not to be considered as linked third parties and do not need to provide the above justifications (1 & 2). ▪ Linked third parties/affiliated entities should be added in section 4.2 of the (Annex 1) DoA Part B under the related beneficiary with an explanation of the third party's work/role, involvement in tasks and WPs, and the amount of budget allocated. 		<p><i>1 Part A. The proof of a legal link between the beneficiary and the LTP has been submitted to IHI via normal Communication in the portal. At the request of the IHI JU, the declaration on joint and several liability was also submitted to IHI via normal Communication in the portal.</i></p>
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2.2 Termination of a participant

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned, or on behalf of the other beneficiaries via an amendment.

The beneficiary's participation will be considered to be terminated on the day after the notification of termination has been submitted to IMI2 JU via the amendment request, even if the amendment is rejected or withdrawn.

Further information is available [here](#).

For all terminations	General requirements and guidance/suggested text for the Description of Action (DoA)	Suggested text Amendment request letter
<p>The following annexes should be modified accordingly.</p> <ul style="list-style-type: none"> ▪ Annex 1 	<p>Annex 1 (DoA) should be updated as follows.</p> <ul style="list-style-type: none"> ▪ Part A: relevant WPs and tasks, effort as PMs. Please note that the terminated participant 	<p><i>The "Name of terminated participant" has terminated its participation on the day after the</i></p>

<ul style="list-style-type: none"> ▪ Annex 2 <ol style="list-style-type: none"> 1. A document with the opinion of the beneficiary whose participation is terminated (or proof that their opinion has been requested) should be uploaded in the Portal by the COO. This can be very brief (one or two sentences). 2. Any supporting documents to justify the termination (if any, e.g. proof of bankruptcy or similar situation; letter from liquidator; court decision, etc). 3. The Amendment request letter should specify the mitigation measures put in place to complete the project. 4. After the termination date, the portal will prompt the terminated beneficiary and the coordinator to draft and submit the termination report in the portal within 30 days. The termination report is similar to the reporting and payment periodic report in the sense that it contains the beneficiary-specific information from the periodic reports (Part B, detailed cost reporting table, CFS, financial statement, use of resources, report on the distribution of payments). Some information must be entered directly in the portal, while some information must be entered in templates to be downloaded and uploaded into the portal. The templates are available directly in the portal. 5. The terminated beneficiary completes its part of the report (encode and signs the financial statements for itself and its linked third parties, update the deliverables, Part B, etc). The termination report must then be submitted as a single package by the coordinator. 	<p>should not be deleted completely if they have contributed to activities and/or used PMs up to the termination. The data should instead be updated to reflect the final status (e.g. reduce the original PMs to the effort actually used in line with the reporting)</p> <ul style="list-style-type: none"> ▪ Part B (PDF): Sections 3.4 Resources to be committed; 4.1 Participants (do not delete the participant but include the status terminated); 4.2 Third parties (as relevant) ▪ Gantt chart (if relevant) ▪ Management structures and governance (if applicable) <p>Annex 2 should be updated. Redistribution of funds should be appropriately reflected in the budget table in the portal.</p> <p>Note: Even if a beneficiary leaves the project prior to the amendment request, the portal will not allow a retroactive termination date to be introduced. Therefore, the termination date is the day after the notification of termination submitted to the JU via the amendment request.</p>	<p><i>notification of termination submitted to the JU via the amendment request”.</i></p> <p><i>This termination has resulted in changes to Annexes 1 and 2.</i></p> <p><i>These are described below:</i></p> <ul style="list-style-type: none"> ▪ redistribution of tasks (if applicable) ▪ redistribution of budget (if applicable) ▪ changes in Annex 1 (DoA) (if changes/ reallocations of tasks and changes to the use of resources are necessary) ▪ changes in Annex 2 <p>The termination of this participant does not impact the capacity of the consortium to deliver the project objectives, because <i>“provide justification”</i>.</p> <p>Note: Please provide information on the major changes but do not repeat details, for example, on the financial figures, PMs and tasks. Please refer to the relevant updated sections of Annex 1 and Annex 2.</p>
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2.2.1 Termination of an EFPIA company/Associated Partner/Other

Please follow the suggested text for all terminations indicated in table at the beginning of this section.

Additional requirements:

For EFPIA companies only: If there is a change in the in-kind contribution, the EFPIA office should be informed accordingly.

The Amendment request letter should explain:

- briefly, how the budget table has been impacted (decrease of total in-kind, non-EU in-kind and financial contribution(s), if applicable) - it may be that the impact on the overall budget following an EFPIA/AP termination is limited if it is compensated by other EFPIA companies/APs joining the project or increasing their contributions;
- how the overall project objectives are still achievable following the termination of the EFPIA company/Associated Partner.

Please follow the general requirements for all terminations indicated in the table at the beginning of this section.

Additional requirements:

Annex 1 (DoA) should be updated as relevant

As relevant, please update all elements related to the withdrawal of the B NRF concerned in the following sections:

- **Table 3.4c** - Financial Contributions (FC) and their justification (from who, to whom and for which tasks, WP);
- **Table 3.4d** - non-EU in-kind (activities and justification);
- **Section 3.4e** - for scientifically relevant activities for generating data in prospective activities during the funded action.

Please follow suggested text for all terminations indicated in the table at the beginning of this section.

Additional requirements:

Following the withdrawal of EFPIA company/Associated Partner X the project EFPIA/AP contributions to the project have changed to the total (amount in EUR)/ the project EFPIA/AP contributions have not changed but the breakdown of contributions has changed. In detail (use applicable options):

- *The EU in-kind contribution is decreased/unchanged*
- *The non-EU in-kind contribution is decreased/unchanged*
- *The financial contribution is increased/decreased/unchanged*

which is reflected in the updated Annex 1 section 3.4 and consistent with the financial information in the budget table in the Portal.

The mitigation measures put in place in order to complete the project are:

- *e.g. redistribution of tasks*
- *e.g. redistribution of resources*
- *e.g. industry compensates with financial contribution to BRF*
- *other EFPIA/AP that compensates totally/partially the financial effects of the withdrawal*

Following the withdrawal of EFPIA company X, EFPIA office has been informed on "include date" on the changes of in-kind contribution (EU and Non-EU) in the project.

2.2.2 Termination of a Beneficiary Receiving Funding (BRF) and a Linked Third Party/Affiliated Entity

Please follow the general requirements and suggested text for all terminations, indicated in the table at the beginning of this section.

2.3 Other types of amendments

2.3.1 Change of beneficiary due to partial takeover (formerly ‘partial transfer of rights and obligations –‘PTRO’s in FP7)

Partial takeovers (‘PT’s) are beneficiary changes due to a partial takeover (i.e. when a part of the business, including the Grant Agreement, is taken over as by another entity, e.g. partial acquisitions; see AGA - Annotated Grant Agreement, art.55).

A simple sale of assets, tangible and/or intangible (including transfer of (some) actions tasks) from the beneficiary to another legal entity without any further transfer of rights and obligations is NOT a takeover.

If a beneficiary is the object of a PT, it needs to be changed in the Grant Agreement through a formal amendment.

Transfers of the GA linked to a universal takeover (‘UT’), -i.e. where the original entity is replaced by a new entity and all rights and obligations — including the GA — are transferred to this new entity, e.g. merger or full acquisition) do NOT require an amendment; an update of the beneficiary data by the LEAR (and validation) in the Participant Register is sufficient.

In case of a PT or UT of a beneficiary receiving JU funding (BRF), in order to add the legal successor as the new BRF, they must be eligible for IMI2 JU funding according to Article 1 of the Commission Delegated Regulation No 622/2014 of 14 February 2014. If they are not eligible for JU funding, the legal successor can remain in the project as a beneficiary not requesting JU funding (BNRF). A beneficiary whose tasks have been taken over should be terminated if it no longer has activities in the project.

General Requirements and guidance	Suggested text Amendment request letter
<p>The following annexes should be modified accordingly</p> <ul style="list-style-type: none"> ▪ Annex 1 ▪ Annex 2 (including Annex 2a, if necessary) <p>The reallocation of tasks and budget, as applicable, should be reflected in Annex 1 and Annex 2.</p>	<p>The letter should specify:</p> <ul style="list-style-type: none"> ▪ The legal situation: <ul style="list-style-type: none"> ✓ the parties participating in the transaction (purchaser and purchased, i.e. the current beneficiary), ✓ the nature of the transaction (whether it’s purchase, partial merger, etc),

General requirements:

Actions in the portal:

- The new entity will replace the original entity as party to the GA (as 'new beneficiary'). The 'transfer date' will be added to the Preamble of the GA.
- The beneficiaries must select the date of the takeover in their amendment request. (If the new beneficiary joins the action, the transfer date must be the same as the accession date. Retroactive dates are only allowed in exceptional cases and with specific justification).
- In a partial takeover, before acceding to the Grant Agreement, the new beneficiary must first register and be validated in the Beneficiary Register unless they already have a validated 'participant identity code' (PIC) and proceed with all requirements as explained in the section "addition of a new participant".
- The legal documents proving the transfer of rights and obligations (takeover contract, court decision, declaration, etc; citation of the applicable rules with hyperlinks to the texts) and summary description of legal situation and consequences for the GA (including financial liability rules) should be provided and uploaded in the Participant Portal Organisation Register (via My Organisation page).
- Best practice: In order to avoid multiple submission of documents, beneficiaries are advised to upload the takeover documents in the Participant Register (via the My Organisation page) and specify in the amendment request that the legal documents are available in the Funding & Tenders Portal. This is particularly useful if several EU Grant Agreements or contracts are affected by a partial takeover.

Notes:

- If the new beneficiary claims that joint and several liability is not correct under the national law governing the PT, please contact your Scientific Officer.

By using the special PT amendment clause, the new beneficiary becomes jointly and severally liable for the former beneficiary's debts. The PT amendment clause doesn't work if the former beneficiary remains in the consortium. In that case, use the normal 'Addition of a beneficiary' clause.

✓ the consequences for the GA (both towards the JU and towards the other beneficiaries).

- The financial liability of the former beneficiary.
- That the legal documents explaining the takeover have been uploaded in the Participant Register (via My Organisation page).

Due to a Partial Takeover of the assets/activities of the "Name of the beneficiary that its activities are taken over", the "Name of new beneficiary" established in "include address" joined the consortium on the date specified in the Annex 1 Part A and "include brief narrative of main task in WPs".

The legal documents proving/explaining the takeover are included in the Participant Portal Organisation Register.

Their addition is important for the implementation of the project because "include justification".

The new participant has the operational capacity to carry out the proposed work because "include justification on operational capacity (e.g. in terms of expertise, infrastructure, data, etc.)".

The total funding allocated to the beneficiary is "include total IMI2 JU funding".

Note: if any budget has been reallocated, please confirm that the relevant sections in Annex 1 and Annex 2 have been updated accordingly.

2.3.2 Addition of new subcontracting

As indicated in the Model Grant Agreement (Art.13), if necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain non-core action tasks described in Annex 1. Subcontracting may cover only a limited part of the action. The beneficiaries must award the subcontracts in line with the conditions established in the MGA, i.e. ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests. Please note that identifying the potential subcontractor in the DoA does not waive the beneficiary’s obligation to be able to demonstrate compliance with the requirements of Article 13 of the MGA. With the acceptance of the amendment, the IHI JU approves that the task may be subcontracted.

It is very important to understand the differences between subcontracts (Article 13) and other contracts for the purchase of goods, works or services (Article 10), which are:

Article 13: Subcontracts	Article 10: Contracts to purchase goods, works or services
<ul style="list-style-type: none"> Subcontracts concern the implementation of action tasks; they imply the implementation of specific tasks which are part of the action. Must be indicated in Annex 1. The price for the subcontracts will be declared as ‘direct costs of subcontracting’ — column B in Annex 2 — in the financial statement; they will not be taken into account for the application of the flat rate for indirect costs. 	<ul style="list-style-type: none"> These contracts do not cover the implementation of action tasks, but they are necessary to implement action tasks by beneficiaries. Do not have to be indicated in Annex 1. The price for these contracts will be declared as ‘other direct costs’ — column D in Annex 2 — in the financial statement; they will be taken into account for the application of the flat rate for indirect costs.

General requirements and guidance	Guidance/suggested text for the Description of Action (DoA)	Suggested text Amendment request letter				
<p>Specific requirements:</p> <ul style="list-style-type: none"> New subcontracting activities should be indicated and justified under the related beneficiary in section 4.2 of the DoA Part B (including subcontracting for EFPIA companies and Associated Partners, both EU and Non-EU), in line with the explanations in the Amendment request letter. When there is more than one subcontracted activity per beneficiary, the estimated amount for each subcontracted activity should be mentioned in Annex 1 (part b) section 4.2 (Third parties involved in the project). Annex 2 should be updated accordingly. 	<p>Suggested text for the DoA, section 4.2:</p> <table border="1"> <thead> <tr> <th>One subcontracting</th> <th>More than one subcontracting</th> </tr> </thead> <tbody> <tr> <td> <p><i>Example of text for section 4.2</i></p> <p><i>A subcontractor will be used to “include activity” to support task 1.4 of WP1. The subcontractor is required because “include justification”.</i></p> </td> <td> <p><i>Example of text for section 4.2</i></p> <p><i>The following subcontractors will be used:</i></p> <ol style="list-style-type: none"> <i>A subcontractor will be used to “include activity” to support task 1.4 of WP1. The subcontractor is required because “include justification” The amount of this subcontracting activity is XXX EUR</i> <i>A subcontractor will be used to “include activity” to support task</i> </td> </tr> </tbody> </table>	One subcontracting	More than one subcontracting	<p><i>Example of text for section 4.2</i></p> <p><i>A subcontractor will be used to “include activity” to support task 1.4 of WP1. The subcontractor is required because “include justification”.</i></p>	<p><i>Example of text for section 4.2</i></p> <p><i>The following subcontractors will be used:</i></p> <ol style="list-style-type: none"> <i>A subcontractor will be used to “include activity” to support task 1.4 of WP1. The subcontractor is required because “include justification” The amount of this subcontracting activity is XXX EUR</i> <i>A subcontractor will be used to “include activity” to support task</i> 	<p>The Amendment request letter should:</p> <ul style="list-style-type: none"> briefly provide a justification and explanation of the new subcontracted activity for the participant, the WPs and tasks concerned; confirm that Annex 1 Part B, section 4.2 and Annex 2 have been updated accordingly
One subcontracting	More than one subcontracting					
<p><i>Example of text for section 4.2</i></p> <p><i>A subcontractor will be used to “include activity” to support task 1.4 of WP1. The subcontractor is required because “include justification”.</i></p>	<p><i>Example of text for section 4.2</i></p> <p><i>The following subcontractors will be used:</i></p> <ol style="list-style-type: none"> <i>A subcontractor will be used to “include activity” to support task 1.4 of WP1. The subcontractor is required because “include justification” The amount of this subcontracting activity is XXX EUR</i> <i>A subcontractor will be used to “include activity” to support task</i> 					

		2.3 of WP2. The subcontractor is required because "include justification". The amount of this subcontracting activity is XXX EUR	
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2.3.3 Addition of a new third party providing in-kind contribution against payment or free of charge (art.11/12 MGA)

As indicated in the Model Grant Agreement, if necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment, or in-kind contributions provided by third parties free of charge.

- In-kind contributions provided by third parties against payment (Art.11). The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded people, contributed equipment, infrastructure or other assets or other contributed goods and services. The third parties and their contributions must be set out in Annex 1.
- In-kind contributions provided by third parties free of charge (Art.12). The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4. The third parties and their contributions must be set out in Annex 1. Even if the beneficiary does not reimburse the third-party for the resources provided, the expected amount of the costs of the third party for providing the in-kind contributions free of charge should be specified in the budget of the beneficiary. Additionally, In-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs by the beneficiary, have to be declared as a receipt in the final period by the beneficiary.

Example (in-kind contribution against payment): Civil servant working as a professor in a public university. Their salary is paid by the government (the ministry) which employs them. According to the secondment agreement, the beneficiary (the university) has to reimburse the government an amount corresponding to the salary paid. The reimbursed amount is a cost for the beneficiary and is recorded as such in their accounts. The beneficiary will declare the amount reimbursed to the government in their financial statements.

Example (in-kind contribution free of charge): Civil servant working as a professor in a public university. Their salary is not paid by the beneficiary (the university) but by the government (the ministry). According to the secondment agreement, the government does not ask any reimbursement in exchange (non-cash donation). The beneficiary will declare these salary costs in their financial statements, even if they are paid by a third party (the ministry/government).

Suppliers of goods, works or services and third parties providing in-kind contributions (against payment or free of charge) do not implement action tasks themselves, but only make resources available to the beneficiary, whereas subcontractors, linked third parties and international partners implement action tasks.

General requirements and guidance/suggested text for the Description of Action (DoA)	Guidance/suggested text for the Description of Action (DoA)	Suggested text Amendment request letter		
<ul style="list-style-type: none"> ▪ New third parties providing in-kind contributions should be specified under the related beneficiary in section 4.2 of the DoA Part B including: <ul style="list-style-type: none"> ▪ the name of the third party ▪ the related Article (Art.11 or Art.12) ▪ the task ▪ the WP concerned ▪ the estimated amount (cost) of the activity ▪ If the third-party contribution is inside or outside the premises of the beneficiary. ▪ Annex 2 should be updated accordingly: The amount of the third-party contribution should be assimilated to beneficiary costs and must be declared in the relevant budget category (personnel costs, other direct costs). Even if the beneficiary does not reimburse the third-party for the provided resources, the expected amount of the costs of the third party for providing the in-kind contributions free of charge should be specified in the budget of the beneficiary. ▪ For third parties providing in-kind contribution (free of charge or against payment) outside the premises of the beneficiary, this amount should be specified in the financial information tab of the related beneficiary in the portal column 'in-kind contribution outside premises' in order not to be included in the indirect costs. <p>Note: In-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs by the beneficiary, will have to be declared as a receipt in final period by the beneficiary.</p>	<p>Suggested text for the DoA, section 4.2: <i>Beneficiary X</i></p> <table border="1" data-bbox="813 363 1391 502"> <tr> <td data-bbox="813 363 1344 502">Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)?</td> <td data-bbox="1344 363 1391 502">Y</td> </tr> </table> <p><i>Third party "Name of the Third Party" for an in-kind contribution against payment (Art. 11). The Third Party will "include activity" to support the work in WP3. The estimated amount of this contribution is EUR XXX, and this has been added to the "personnel/other direct costs" of the beneficiary. The activity will take place within the premises of the beneficiary.</i></p>	Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)?	Y	<p>The Amendment request letter should specify:</p> <ul style="list-style-type: none"> ▪ The participant concerned ▪ The name of the third party ▪ A justification and explanation of the new third-party activity.
Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)?	Y			

2.3.4 Change to Annex 1 and Annex 2

(1) Change to Annex 1 - other changes not covered in the previous sections

The following annexes should be modified accordingly:

- Annex 1
- Annex 2 (if a change in the estimated budget is necessary)

Requirements:

- The proposed changes should not deviate from the original project objectives.
- Depending on the requested change, Annex 1 (DoA) should be updated.

Update	Examples of requested changes	Section to be updated	Suggested text for the Amendment request letter
Milestones and deliverables	Change of Description Change of due date Removal/Addition	Portal Part A – Milestones tab Part B – Gantt chart	<p>Examples</p> <ul style="list-style-type: none"> ▪ Milestone/Deliverable D1.3 has been delayed due to “include justification”. ▪ A new deliverable D2.5 has been included “include justification”. <p>- Task 1.4 has been included under WP1 in order to “include justification”. This new task is in line with the project objectives. Beneficiaries X will perform this task. If applicable, the associated budget is no longer needed by beneficiary Y because “include justification”.</p> <p>Note:</p> <ul style="list-style-type: none"> ▪ All changes in Annex 1 (DoA) should be justified in the Amendment request letter. ▪ When the changes in Annex 1 affect the distribution of the budget, Annex 2 should be updated accordingly. Justifications regarding the budget redistribution should be provided in the Amendment request letter, without repeating the financial figures, but the letter
Critical risks	Descriptions and/or addition of new risks	Portal Part A – Critical risks tab Part B – if relevant	
Work packages	Changes of WP objectives Changes in tasks Changes in beneficiaries involved Changes in staff effort Changes in deliverables (Change of Description, Change of due date, Removal/Addition) Updates of information on clinical study originally planned	Portal Part A – Work Packages tab Portal Part A – Effort Portal Part A – Deliverables tab Part B – Gantt chart and as relevant Part B – update clinical trial annex as relevant including the 3 mandatory deliverables	
Other direct costs (ODC)	Changes in other direct costs	Portal Part A – Financial information tab of the related beneficiaries Part B – Section 3.4 (including related WPs)	
Financial contributions	Changes in financial contributions from EFPIA/AP to BRF	Portal Part A: - Participant providing FC: ✓ Financial information tab (FC paid) - Participant receiving FC:	

		<ul style="list-style-type: none"> ✓ Financial information tab (FC received) and Annex 2 (total cost, if applicable). ✓ Part B – Section 3.4.c <p>Note: More information under point 2.2.2</p>	<p>should clearly mention if there has been an increase, decrease, change in breakdown and for which beneficiaries, and confirm that the financial figures are those in the relevant tables (specify which ones) and in the Annex 2/Budget table in the Portal.</p>
Non-EU In-kind	Changes of in-kind contributions (EU and non-EU)	<p>Portal Part A – Financial information Tab of the related beneficiaries</p> <p>Part B – Section 3.4.d (Non-EU task)</p> <p>Note: More information under point 2.2.2</p>	

(2) Change of Annex 2 – (estimated budget)

IMI2 specific columns - Changes in Annex 2 occur in combination with modifications in Annex 1.

The Amendment request letter should specify all changes and redistributions of the budget across beneficiaries with relevant justifications.

Attention: A change of the action’s estimated eligible costs requires the intervention of the IHI Officer. Please inform them accordingly.

2.3.5 Extension of duration, change of reporting periods

General requirements	Guidance for the Description of Action (DoA)	Suggested text Amendment request letter
<p>The following elements should be modified accordingly</p> <ul style="list-style-type: none"> ▪ Action’s duration ▪ Annex 1 (description of the action) ▪ Reporting periods 	<p>Annex 1 (DoA) should be updated with the new duration and reporting periods and the following elements should be aligned:</p> <ul style="list-style-type: none"> ▪ Deliverable updates (description and due date) ▪ Milestone updates (description and due date) ▪ Risk management updates, if applicable ▪ Work package updates and timelines ▪ Gantt charts and other figures 	<p>The letter should set out the new duration and new reporting periods with an appropriate justification (for a project duration extension, it is enough to mention that justification has been provided in the letter sent to the IHI JU ED dated <u>DDMMYYYY</u>)</p>

Guidelines to request a project extension of more than 3 months

The coordinator of the project should first consult the project's SO and then prepare a notification (normal communication through the portal) for pre-approval by the IHI Executive Director. Once the SO obtains the positive feedback internally, they shall give the green light to the COO to submit the amendment and proceed with the overall amendment assessment.

Template for the (normal) notification to IHI JU

Dear Executive Director,

We are writing you to request a XX-month, no-cost, extension, of the <Acronym> project.

This would mean that the new requested end date of the project will be the dd/mm/yyyy.

We realise that this request could have the following impacts: e.g. later delivery and closing of the project, project objectives and their impacts, etc.

The main rationale for our extension request is/are listed below. The annex to this letter presents the status of the project and the list of delayed tasks and deliverables/milestones.

Please provide all information below:

1. Explain the background and key reasons for asking for the extension.
2. Justify the requested duration of the extension.
3. Explain how the beneficiaries tried to mitigate the situation causing the delay or need for extension.
4. Explain the essentiality of your request and the consequences in case the extension is not granted (refer clearly to project objectives AND impacts as in the DoA).
5. Confirm and justify that the objectives of the projects remain achievable and scientifically relevant within the new planned timelines.
6. Comment on the way resources have been managed so far (IMI2 JU funding and EFPIA [and Associated Partner] contributions) and confirm that all partners have agreed to the extension and are aware that also the final payment will be delayed accordingly.
7. Confirm that partners are able to continue with the project until the extended end date and all governance activities can continue as planned.

We can provide additional background information about this request if needed.

Sincerely, on behalf the <Acronym project> Consortium,

<Name of the Coordinator>

Annex

Please provide a summary on the status of the project so far.

List all delayed tasks/deliverables/milestones for each WP and provide new timelines.

WPs	Tasks/deliverable/milestone	Month

Annex 1 – Amendment clauses

Amendment clauses	Description
AT1	Removal of beneficiaries due to their non-accession to the GA
AT2	Removal of a beneficiary whose participation was terminated
AT3	Addition of a new beneficiary
AT4	Change of beneficiary due to partial takeover
AT5a	Removal of a linked third party
AT5b	Removal of an international partner
AT6a	Addition of a linked third party
AT6b	Addition of an international partner
AT7a	Change concerning a beneficiary/linked third party 'not receiving EU funding'
AT8	Change of coordinator
AT9a	Change of the option for 'authorisation to administer'
AT22	Change of the action's title and/or acronym
AT23	Change of the action's duration
AT24	Change of the action's starting date
AT25	Change of reporting periods
AT28	Change of the participation in the Research Data Pilot
AT29	Change to the Commission/Agency right to object to transfers or licensing
AT30	Change concerning the security context
AT36	Change concerning specific cost categories ('specific unit costs')
AT37	Change concerning financial support to third parties
AT38	Change of the pre-financing
AT39	Change of the amount of the contribution to the Guarantee Fund
AT40	Change of bank account for payments
AT49	Change concerning transnational/virtual access to research infrastructure
AT51a	Change of the applicable law

AT51b	Change of the option for 'dispute settlement'
AT54	Change of the option for complementary grants
AT55	Change of the option for joint actions
AT56	Change of the beneficiary/partner short name
N/A	Change of Beneficiary Details (legal name, legal address, VAT, ...)
N/A	Change of legal status
N/A	Universal Transfer

Selected by EU (IHI JU)

Amendment clauses	Description
AT21	Changes of Annex 1 (description of the action)
AT26	Resuming the action after suspension
AT31	Changes of Annex 2 (estimated budget of the action)
AT32a	Decrease in the maximum grant amount
AT32b	Increase in the maximum grant amount
AT34	Change to the action's estimated eligible costs

On Demand

Amendment clauses	Description
AT60	Change due to errors/mistakes

