Periodic technical report – Part A

PERIODIC REPORT OF THE ACTION

Grant Agreement number:
Action acronym:
Action title:

Periodic report: 1st □ 2nd □ 3rd □ 4th □
Period covered: from to
Start date of the action
Duration of the action:

Date of submission:
Version:

Action website address:

The report is elaborated on the basis of the:

- **Original Grant agreement**
- **Amended Grant Agreement through amendment n° x**

Declaration of the coordinator

I, the coordinator of the <GA number>-<Acronym> project, declare that,

- The periodic report submitted is in line with the obligations as stated in Article 20 of the Grant Agreement:
- The attached periodic report represents an accurate description of the work carried out in this project for this reporting period;
- The project (tick as appropriate):
  - □ has fully achieved its objectives and technical goals for the period
  - □ has achieved most of its objectives and technical goals for the period with relatively minor deviations
  - □ has failed to achieve critical objectives and/or is not at all on schedule
- The public project website <address> is up to date, if applicable.
- To my best knowledge, the financial statements which are being submitted as part of this report are in line with the actual work carried out and are consistent with the report on the resources used for the project and if applicable with the certificate on financial statement.
- All participants have declared to have verified their legal status. Any changes or deviations have been reported to the Beneficiary Register, and to the IMI2 JU via the coordinator in accordance with Article 17.2 of the Grant Agreement.

Name of the Coordinator: Firstname Secondname

Date: dd Mmm YYYY

Signature of the Coordinator: …….

1. Summary for publication

This section must be of suitable quality to enable direct publication by the Commission/IMI2JU. It should be easy to read i.e. written in a language easily understandable by a broader public, thereby promoting the dissemination and supporting the exploitation of EU funded results. It should preferably not exceed 7480 characters (equivalent to two pages of a text document). This part must not contain any confidential data.

The summary for publication must be drafted as a "stand-alone" text. No references should be made to other parts of the report. References can be made only to publicly available information.

For each periodic report, a separate summary for publication must be prepared by updating the summary of the last reporting period.

Beside the summary filled within the tool, diagrams or photographs illustrating and promoting the work of the action can be provided (only as images)[1].

This summary will be automatically published on IMI's website and should be also published on the action's public website.

1.1 Summary of the context and overall objectives of the action

1.2 Work performed from the beginning of the action to the end of the period covered by the report and main results achieved so far

1.3 Progress beyond the state of the art and expected potential impact (including the socio-economic impact and the wider societal implications of the action so far)

1.4 Address (URL) of the action's public website

[1] Any rights of third parties must be cleared in advance in accordance with the GA.

2. Deliverables

The deliverables due in this reporting period have to be uploaded by the respective lead beneficiaries in the IT tool. Add justifications for missing deliverables or not sub mitted on time. If a deliverable has been cancelled or regrouped with another one, please indicate this in the column "Comments".
This table is cumulative, i.e. it should always show all deliverables from the beginning of the action.

Del. no.	**Deliverable name**	**WP no.**	**Lead beneficiary**	**Type**	**Dissemin. level**	**Delivery date from Annex 1**	**Actual delivery date**	**If deliverable not submitted on time: Forecast delivery date if appropriate**	**Status**	**Comments**
[insert deliverable number]	[insert deliverable name]	[insert WP number]	[insert beneficiary short name]	*[*R*]* *[*DEM*]* *[*DEC*]* *[*OTHER*]*	*[*PU*]* *[*CO*]* *[*CI*]*	[insert month number]	[insert dd/mm/yyyy]	[insert dd/mm/yyyy]	*[*Not submitted*]* *[*Request for revision*]* *[*Not assessed yet*]* *[*Not valid*]* *[*Accepted*]*	[insert comments, if a due deliverable is not submitted at the moment of the submission of a periodic report, or any other relevant comment]

3. Milestones

This table is cumulative; it should show all milestones from the beginning of the action.

Milest. no.	Milestone title	Related WP(s) no.	Lead beneficiary	Delivery date from Annex 1	Means of verification	Achieved	If not achieved Forecast achievement date	Comments
[insert MS number]	[insert milestone name]	[insert WP number]	[insert beneficiary short name]	[insert dd/mm/yyyy]	[insert means of verification as in Annex 1]	*[*YES*]* *[*NO*]*	[insert dd/mm/yyyy]	[insert comment if needed]

4. Ethical Issues (if applicable)

The ethics requirements, set during the full proposal ethics screen or review, should be inserted here. The implementation of those requirements needs to be reported upon as follows.

Ethic requirements	**Due date of the compliance of the ethic requirement**	**Report of the independent ethics advisor/ advisory board if applicable**	**Comments**
[insert requirement as in Annex 1-DoA]	[insert dd/mm/yyyy]	*[*Not submitted*]* *[*Submitted*]*	[insert comment if a due ethic requirement is not cleared at the moment of the submission of the periodic report, or any other relevant comment]

5. Critical implementation risks and mitigation actions

At the end of each period beneficiaries should give the state of play of every risk identified in Annex 1 and if necessary give new mitigation measures. There is a possibility to add new risks without the need to make an amendment to the GA.

Risk number	**Description of risk**	**WP concerned**	**Proposed risk-mitigation measures**	**State of the Play**					
				Period 1			**Period 2, 3, etc**		
				Did you apply risk mitigation measures	**Did your risk materialised**	**Comments**	**Did you apply risk mitigation measures**	**Did your risk materialised**	**Comments**
[insert risk number as in Annex 1]	[insert risk description as in Annex 1]	[insert WP number]	[insert mitigation measure as in Annex 1]	*[*YES*]* *[*NO*]*	*[*YES*]* *[*NO*]*	[insert comment if needed]	*[*YES*]* *[*NO*]*	*[*YES*]* *[*NO*]*	[insert comment if needed]

6. Dissemination and exploitation of results

6.1 Scientific publications

Each beneficiary must ensure open access (free of charge, online access for any user) to all peer-reviewed publications relating to its results (article 29.2 of the GA. Beneficiaries are free to deposit their peer-reviewed publications[2] in those repositories which are most appropriate for their subject and publication.[3] However, publications related to the action must be reported continuously via one of the following three ways:

1. In case of publications potentially related to the action and which are already accessible via OpenAIRE[4,] references to these publications (with link to the project ID) are displayed in the reporting section of the Participant Portal for the project. The beneficiaries will have to check if these references are directly linked to the work performed within the project and then, if it is the case, such publications should be ticked as relevant and will then be included in the table of publications issued at the time the periodic report is generated (see below).

2. In case of publications related to the action that were not registered via OpenAIRE, the beneficiary encodes in the reporting IT tool the Digital Object Identifier[5] (DOI) and then all the other columns of the table below are filled automatically.

3. For the publications neither accessible via OpenAIRE nor having DOI, the beneficiary has to complete manually the full set of reference data.

In addition to the data provided via the DOI, beneficiaries must answer a number of other questions (related to peer-review status, participation of public and private entities to the publication and information on open access).

The column related to open access must be answered with one of these three options (Green OA: Access is granted after an embargo period, Gold OA: Paid Open Access as processing charges).

- Yes Green OA / specify the length of embargo if any
- Yes Gold OA/Specify the amount of processing charges if any in €
- No

All publications must include the statement set out in the GA that the results were generated with the assistance of financial support from the Innovative Medicines Initiative 2 Joint Undertaking which receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA [and[insert name of the associated partner]] (see article 38.1.2 of the Grant Agreement).

[2] Peer-reviewed' publications refer to publications that have been evaluated by peers, i.e. other scholars. The dominant type of peer-reviewed scientific publication is the journal article, for which open access in mandatory in Horizon 2020. In addition, however, beneficiaries are strongly encouraged to provide open access to other types of scientific publications, some of which may, in some cases, not be peer-reviewed, including monographs, books, conference proceedings and grey literature (informally published written material not controlled by scientific publishers, e.g. reports).

[3] For instance a thematic repository or an institutional repository.

[4] OpenAIRE links and federates existing repositories. As such it provides access to publications that have been deposited in all repositories that are technically interoperable with OpenAIRE ("OpenAIRE compliant")

[5] DOI: Digital Object Identifier – Permanent identifier which should be a persistent link to the published version full text or abstract (if article is pay per view) or to the final manuscript accepted for publication (link to article in repository).

Type of scientific publication	Title of the scientific publication	DOI	ISSN or eSSN	Authors	Title of the journal or equivalent	Number, date	Publisher	Place of publication	Year of publication	Relevant pages	Public & private participation	Peer-review	Is/Will open access provided to this publication	List contributing beneficiary organisations
*[*Article in journal*]* *[*Publication in conference proceeding/workshop*]* *[*Books/Monographs*]* *[*Chapters in books*]* *[*Thesis/dissertation*]*	[insert title of the publication]	[insert DOI reference]	[insert ISSN or eSSN number]	[insert authors' name(s)]	[insert title of the journal]	[insert number of the journal] [insert month of the publication] [insert year of the publication]	[insert name of the publisher]	[insert place of publication]	[insert year of the publication]	[insert first page of the publication] - [insert last page of the publication]	*[*YES*]* *[*NO*]*	*[*YES*]* *[*NO*]*	*[*Yes - Green OA [insert the length of embargo if any]*]* *[*Yes - Gold OA [insert the amount of processing charges in EUR if any]*]* *[*NO*]*	

6.2 Dissemination and communication activities

List only activities directly linked to the Action.

Number	Type of dissemination and communication activities	Type of audience reached In the context of all dissemination & communication activities ('multiple choices' is possible)	Estimated Number of persons reached
1	*[*Organisation of a Conference*]* *[*Organisation of a workshop*]* *[*Press release*]* *[*Non-scientific and non-peer reviewed publications (popularised publications)*]* *[*Exhibition*]* *[*Flyers training*]* *[*Social media*]* *[*Web-site*]* *[*Communication campaign (e.g radio, TV)*]* *[*Participation to a conference*]* *[*Participation to a workshop*]* *[*Participation to an event other than a conference or workshop*]* *[*Video/film*]* *[*Pitch event*]* *[*Participation in activities organised jointly with other H2020 project(s)*]* *[*Other*]*	Scientific Community (higher education, Research)*]* *[*Industry*]* *[*Civil Society*]* *[*General Public*]* *[*Policy makers*]* *[*Social media*]* *[*Medias*]* *[*Investors*]* *[*Other*]*	

6.3 Intellectual property rights resulting from the project

The applications for patents, trademarks, registered designs, etc. shall be listed according to the template provided hereafter. The list should specify at least one unique identifier (ex: European Patent application reference). This table is cumulative, which means that it should always show all applications from the beginning until after the end of the action.
One IPR can have several IP organisations, identifiers, and even more applicants. In the case of multiple applications covering the same IP (e.g. the same invention), in different offices, the beneficiary should only indicate one. If an application is filed with the EPO, only this application should be mentioned. If not, only the first application should be reported. The same principle applies to the publication number of award of protection.

Type of IP Rights	**Application reference**	**Date of the application**	**Official title of the application**	**Applicant(s)**	**Has the IPR protection been awarded?**	**If available, official publication number of award of protection**
*[*Patent*]* *[*Trademark*]* *[*Registered design*]* *[*Utility model*]* *[*Other*]*	*[Option for international applications of patents* [insert IP international organisation code] [insert serial number]*]* *[Option for national applications of patents* [insert country code (two letters)] [insert serial number]*]* *[Option for other registered IPR* [insert application reference country code (two letters) or organisation code)] [insert alfa numeric identifier]*]*	[insert dd/mm/yyyy]	[insert title of the application]	[insert beneficiary(ies) name]	*[*YES*]* *[*NO*]* *[*No applicable*]*	*[Option for patents* [insert code (two letters referring to a country or organisation)] [insert serial number]*]* *Option for rest* [insert official publication number]*]*

6.4 Innovation

Explanation of the terminology

	Explanation
Innovation	Innovation is an introduction within a firm or market of a new or significantly improved product (good or service), process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relation. The minimum requirement for an innovation is that the product, process, marketing method or organisational method must be new (or significantly improved) to the firm.
Prototype, testing activities	Proofs of S&T feasibility: Results of innovation activities that lead to confirmation/verification of technical feasibility of new products and processes in a (near to) operational environment. It includes prototypes and demonstrations of new products and processes, results of testing/piloting with users, trial production and pilot plants in manufacturing as well as trials and testing activities for the provision of services, such as tests of how the provision of services functions with the use of new technologies or trials to examine the performance of significant improvements in existing services.
Clinical trials	Clinical trials are systematic tests on human volunteers to ensure that new drugs, vaccines or treatments are both safe and effective and can be introduced on the market.
Product	Good or service introduced to the market or to the company/organisation that is new or significantly improved with respect to its capabilities, user friendliness, components or sub-systems. A good is usually a tangible object such as a smartphone, furniture, or packaged software, but downloadable software, music and film are also goods. A service is usually intangible, such as retailing, insurance, educational courses, air travel, consulting, etc.
Process	New or significantly improved production process, distribution method, or supporting activity that was implemented within an organisation.
Method	New organisational method or implementation of a new marketing concept or strategy in enterprises' business/organisation practices (including knowledge management). The organisational method covers workplace organisation or external relations that have not been previously used by your enterprise/organisation. The new marketing method requires significant changes in product design or packaging, product placement, product promotion or pricing that has not been used before.

Does the project include the following activities and if so how many of each?

Activities developed within the project	**Number**
Prototypes	[insert number]
Testing activities (feasibility/demo)	[insert number]
Clinical trials	[insert number]

Will the project lead to launching one of the following into the market (several possible):

New product (good or service)	*[*YES*]* *[*NO*]*
New process	*[*YES*]* *[*NO*]*
New method	*[*YES*]* *[*NO*]*

7. Impact on SMEs

The following table is cumulative and will be filled at the end of each reporting period.

SME Name	Turnover of the company at the beginning of the project/most recent accountability period from the beginning of the project	Number of employees at the beginning of the project/ most recent accountability period from the beginning of the project	Turnover of the company at the most recent accountability period	Number of employees at the most recent accountability period
[insert name of SME]	[insert amount from database]	[insert number from database]	[insert amount]	[insert number]

8. Open Research Data

A new element in Horizon 2020 is the use of Data Management Plans (DMPs) detailing what data the project will generate, whether and how it will be exploited or made accessible for verification and re-use, and how it will be curated and preserved. The use of a Data Management Plan is required for IMI projects. In order to support the data management life cycle for all data that will be collected, processed or generated by the project.

Digital Object Identifier, DOI (if available)	**Title/Identifier (if no DOI available)**	**Is this dataset Openly accessible[6]?**	**Is this dataset re-usable[7]**	**If the dataset is linked to a publication, specify the DOI of the publication**
[insert DOI reference]	[insert title or identifier]	*[*YES*]* *[*NO*]* *[upon request]*	*[*YES*]* *[*NO*]*	[insert DOI reference of the publication]

[6] Accessible means Open Access defined as free of charge access for anyone via Internet. Answer "yes" if the open access to the data is already established or if it will be established after an embargo period.

[7] Re-usability has 2 aspects: 1) technical: the technical standards used are compatible 2) legal: the necessary rights are in place for other users to use the dataset.

9. Gender

Gender of R&D participants[8] involved in the project
For MSC Actions, all parts of the table below are automatically filled and beneficiaries don't have to fill this part.

Beneficiaries	Number F including third parties (if appropriate)	Number M including third parties (if appropriate)	Total Including third parties (if appropriate)
[insert name of beneficiary]	[insert number]	[insert number]	[insert number from GA data]

Gender dimension in the project
Does the project include a gender dimension in research[9]? *[*YES*][*NO*]*

[8] Participants are defined as people actively participating and paid by the EU project.
[9] Gender dimension in research is a concept regrouping the various elements concerning biological characteristics and social/cultural factors of both women and men into the development of research policies, programmes and projects.

Financial Periodic Report

Implementation

Individual financial statements (Annex 4 to the GA) must be filled in by each beneficiary and by linked third parties.[10]

Financial statements must be sent to IMI as part of the periodic reports. If a beneficiary does not include its related financial statement in a periodic report, the costs will be considered 'zero' for this reporting period but the beneficiary can declare its costs with the next financial report (for the next reporting period).

Explanation of the use of the resources and financial statements:
Each beneficiary must provide explanation of the use of resources in the financial statement.

A. Direct personnel costs

For each beneficiary, the only data requested is the Person-months per Work-Package (not per deliverable).

At this stage, the beneficiary does not have to provide names, level of experience, etc[11]
Personnel costs of SME owners without a salary and of beneficiaries that are natural persons not receiving a salary reimbursed on the basis of unit costs have to be declared in column A.4.

B. Direct costs of subcontracting

The total direct costs for the period have to be broken down into the costs for individual subcontractants in the the column B.

- Unforeseen subcontracting not indicated in the grant agreement - For the exceptional case of subcontracting not indicated in annex 1, in addition to the information provided in the technical report (par.1.2), the beneficiary shall specify in this section the cost for each subcontract.

A + D Direct costs of Third Parties (not linked third parties)

Direct cost related to in-kind contributions provided by third parties should be declared in the the personnel and/or other direct costs columns, depending of the type of cost.

- Unforeseen (not indicated in the grant agreement) use of in kind contribution from third party against payment or free of charge

For the exceptional case of use of in-kind contributions provided from a third party against payment or free of charge, not indicated in advance in Annex 1, in addition to the information provided in the technical report (par.1.2), the beneficiary shall specify in this section the cost of the resources.

C. Direct cost of financial support

Direct cost concerning the financial support to ("cascade funding" and prizes) (article 15 of the GA) third parties should be declared in the column C.

[10] Beneficiaries identified in the Grant Agreement as not receiving JU funding are not subject to such obligation.
[11] Complementary information may be requested later in specific cases.

D. Other direct costs

Cost related to contracts to third parties for the provision of goods, works or services have been provided in column D (Article 10 of the GA).

1. If costs declared under "other direct costs" are equal to or less than 15% of claimed personnel costs for the beneficiary for that reporting period, then, no explanation needs to be provided (but beneficiaries must in any case keep all justifications in order to prove the costs they declare as eligible in case of check and audit).

2. If costs declared under "other direct costs" are higher than 15% of claimed personnel costs for the beneficiary for that reporting period, then other major direct cost items12 need to be explained by the beneficiary in the table provided in the column D. The explanations must be up to the level that the remaining costs are below 15% of personnel costs. Explanations should be given starting from the cost items of highest value in terms of cost amount.

If other direct cost items are reported, the beneficiary must provide:
a. if foreseen in DoA: simple reference to DoA
b. If not foreseen in DoA: cost/amount per item, description of the item, nature of item (travel, equipment, other goods & services), work package(s), project relevance/explanation

Example:

Personnel costs: 100000€
Other directs costs: 35000€
Since the other direct costs represent 35% of the personnel costs, then for 20% of other direct costs, justification have to be given i.e for 20000€.
So if the 35000€ is the sum of items recorded in the accounts eg. 8500€ + 7500€ + 6500€ + 5500€ + 4000€ + 3x1000€, the beneficiary has to list and justify the items of 8500€, 7500€ and 6500€. The remaining amount (12500€) is below 15% of the personnel costs and remains undetailed.

F. Specific costs

This category can be used to report individual specific cost (as costs for energy efficiency measures in buildings', access costs for providing trans-national access to research infrastructures, costs for clinical studies) reimbursed on the basis of unit costs.

[12] An item is considered as a cost declared in the accountability book of each beneficiary according to their internal accountancy practices.

Additional information

There is also a possibility to declare again the different third party costs which need to be removed from the total eligible costs of the beneficiary for the calculation of the indirect costs (e.g. subcontracting, costs of in-kind contributions from third parties but only those which are not used on the premises of the beneficiary, costs of providing financial support to third parties, unit costs, lump sums - Article 6.2.E).

Scheme

Costs of in kind contributions of 3rd party not used on premises: 1, 2 mentioned again here for information since the indirect cost should not be paid to the beneficiary

F. Specific costs
SP1, SP2 as per DoA

C. Financial Support to Third parties :
TP1 TP2
TP1

print format A4 landscape

MODEL ANNEX 4 FOR GENERAL ...GA - MULTI-BENEFICIARY

FINANCIAL STATEMENT FOR *[BENEFICIARY [name]/ LINKE... THIRD PARTY [name]]*

Eligible* costs (per budget category)														Receipts	EU contribution			Additional information
A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs		E. Indirect costs	*[F. Costs of ...]*		Total costs	Receipts	Reimbursement rate %	Maximum EU contribution ***	Requested EU contribution	Information for indirect costs :
A.1 Personnel A.2 Natural persons under direct contract A.3 Seconded persons *[A.4 Personnel for providing access to research infrastructure]*	A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary					D.1 Travel D.2 Equipment D.3 Other goods and services	D.4 Costs of large research infrastructure		*[F.1 Costs of ...] ** *	*[F.2 Costs of ...]** *		Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
form of costs**	Actual	Unit ①	Unit	Actual	Actual	Actual	Actual	Flat rate ⑨	Unit ④	Unit ⑤						
			XX EUR/hour					25%	XX EUR/unit							
		Total (b)	No hours	Total (c)	(d)	(e)	(f)	(g)	(h)=0,25x[(a)+(b)+(c)+(d)+(e)+(f)+(g)]* [(i1)]⑥+[(i2)]⑥ (o))	No units	Total (i1)	Total (i2)	(j) = (a)+(b)+(c)+(d)+(e)+(f)+(g)+(h)+(i1)+(i2)	(k)	(l)	(m)	(n)	(o)

A. Personnel costs:
Persons/month per WP
WP1
WP2
WP n

B Subcontracting
SC1
SC2
Unforeseen - Subcontracting
USC1 €
USC2 €

In A & D
In kind contribution from third party against payment & free of charge as well as unforeseen use of in kind contribution from third party against payment & free of charge, should be included in the total amount of the beneficiary.

D. Other direct costs: explanation of major cost items if the amount exceeds 15% of personnel costs:

Item Description	Cost €	Nature of item (drop down list: travel, equipment, other goods & services)	WP …	Explanation if not foreseen in Annex 1
Item X				
Item Y				
	Remaining amount			

Explanations on the use of resources

Period [insert period number]
([insert first date of period dd/mm/yyyy - insert end date of period dd/mm/yyyy]

Project Number: [insert project number]

Acronym: [insert acronym]

Beneficiary [insert beneficiary number] - [insert beneficiary name]			
Direct personnel costs declared as actual costs			
Persons months per WP			
Person months		Associated WP	
[insert number pm]		[insert WP number]	
Use of in kind contribution from third party			
Costs	Third Party name (Explanations)	Type	Foreseen in Annex 1
[insert amount in EUR]	[insert comment]		*[*YES*]* *[*NO*]*
Direct costs of subcontracting			
Costs	Explanation		Foreseen in Annex 1
[insert amount in EUR]	[insert comment]		*[*YES*]* *[*NO*]*
Financial support to third parties			
Costs		Explanation	
[insert amount in EUR]		[insert comment]	
Other direct costs: explanation of major cost items if the amount exceeds 15% of personnel costs			
Costs	Short description	Category	Associated WP	Explanation (if not included in Annex 1)
[insert amount in EUR]	[insert comment]	[Travel] [Equipment] [Other goods & services]	[insert WP number]	[insert comment]

Use of in kind contribution from third party				
Costs	Short description	Category	Associated WP	Explanation (if not included in Annex 1)
[insert amount in EUR]	[insert comment]	[Travel] [Equipment] [Other goods & services]	[insert WP number]	[insert comment]

Specific costs	
Costs	Short Description (as per Annex 1)
[insert amount in EUR]	[insert comment]

Receipts (Article 5.3.3 of the GA) including financial contribution received from an EFPIA company/IMI2 associated partner [column (k) of the financial statement]	
Costs	Please indicate type of receipt or name of organisation providing the in-kind/financial contribution
[insert amount in EUR]	[insert Name/comment]

[insert table above as many times as number of beneficiaries]

[Option for Projects under grants of more than 5 million € for which a pre-financing is paid and the reporting periods for interim payments of the balance exceed 18 months (Article 20.5 of the GA)

Information on cumulative expenditure incurred

Beneficiary	**Year**				
	1	**2**	**3**	**4**	**n**
[insert beneficiary name]	[insert cumulative expenditure incurred by the beneficiaries from the start date of the action]	…			
[insert beneficiary name]	[insert cumulative expenditure incurred by the beneficiaries from the start date of the action]	…			
…	…				

Periodic technical report – Part B

Project[13] Number: [insert project reference number]
Project Acronym: [insert acronym]
Project title: [insert project title]

Period covered by the report: from [insert dd/mm/yyyy] to [insert dd/mm/yyyy]
Periodic report: *[1st] [2nd] [3rd] [4rd] [*Final*]*

Reference to the relevant Description of the Action

[13] The term 'project' used in this template equates to an 'action' in certain other Horizon 2020 documentation

1. Explanation of the work carried out by the beneficiaries and Overview of the progress

- Explanation of the work carried out during the reporting period in line with the Annex 1 to the Grant Agreement.
- Overview of the project results towards the objective of the action in line with the structure of the Annex 1 to the Grant Agreement including summary of deliverables and milestones, and a summary of exploitable results and an explanation about how they can/will be exploited[14].

(No page limit per workpackage but report shall be concise and readable. Any duplication should be avoided).

1.1 Objectives

List the specific objectives for the project as described in section 1.1 of the DoA and described the work carried out during the reporting period towards the achievement of each listed objective. Provide clear and measurable details.

1.2 Explanation of the work carried per WP

1.2.1 Work Package 1

Explain the work carried out in WP1 during the reporting period giving details per participant involved.

1.2.2 Work package 2

etc.

1.3 Impact

Include in this section whether the information on section 2.1 of the DoA on how your project will contribute to the expected impacts is still relevant or needs to be updated. Include further details in the latter case.

1.4 Consortium management

Please describe the overall management of the project during the period, highlighting any success factors and/or challenges that have arisen within the team and indicate how these challenges have been resolved. Summarise, if any, the major changes in the composition of the consortium, and if these have created difficulties for the progress of the project, please explain the approach taken to resolve them.

Please describe if any interactions with relevant stakeholders occurred during the period or are foreseen, including Regulators, Health Technology Assessment Bodies and patients organisations.
In particular, when relevant, please indicate if the consortium has taken any actions to interact with the Regulators in the context of qualification advice/opinion procedures.

Please comment on the aspects related to the public private partnership (PPP) during the period i.e. added value of the collaboration on the project or leverage effect if any.

[14]Recital 33 of H2020 the rules of participation(33) : Rules governing the exploitation and dissemination of results should be laid down to ensure that participants protect, exploit and disseminate those results as appropriate, and to provide for the possibility of additional exploitation conditions in the European strategic interest. Participants that have received Union funding, and that plan to exploit the results generated with such funding primarily in third countries not associated with Horizon 2020, should indicate how the Union funding will benefit Europe's overall competitiveness (reciprocity principle), as set out in the grant agreement.

1.5 Collaborations/synergies with other initiatives

Please describe here any activities related to collaboration with other relevant initiatives occurred during this period.

2. Update of the plan for exploitation[15], dissemination and sustainability of results

Include in this section whether the plan for exploitation, dissemination and sustainability of results as described in the Annex 1 (DoA) needs to be updated and give details.

3. Update of the data management plan

Include in this section whether the data management plan as described in the Annex 1 (DoA) needs to be updated and give details.

4. Follow-up of recommendations and comments from previous review(s) (if applicable)

Include in this section the list of recommendations and comments from previous reviews and give information on how they have been followed up.

5. Deviations from Annex 1 (if applicable)

Explain the reasons for deviations from Annex 1, the consequences and the proposed corrective actions.

5.1 Tasks

Include Explanations for tasks not fully implemented, critical objectives not fully achieved and/or not being on schedule. Explain also the impact on other tasks on the available resources and the planning.

5.2 Use of resources

Include explanations on deviations of the use of resources between actual and planned use of resources in Annex1, especially related to person-months per work package.

5.2.1 Unforeseen subcontracting (if applicable)

Exceptionally, the IMI2 JU may approve costs related to subcontracts not included in Annex 1 and 2 without formally amending the Grant Agreement (GA) under the conditions set out in Article 13.1 of the GA, if the circumstances are explained and justified by the beneficiary in this section.

- The approval is at the discretion of the IMI2 JU, and there is no automatic entitlement to it. Therefore, beneficiaries that do not amend the GA to include subcontracting assume the risk of non-approval by the IMI2 JU and rejection of costs.

[15] In accordance with article 25.3 of the IMI2 model grant agreement, exploitation shall be understood as follows:
(a) 'research use' means the use of results or background needed to use results, for all purposes other than for completing the action or for direct exploitation and which includes but is not limited to the application of results as a tool for research, including clinical research and trials and which directly or indirectly contributes to the objectives set out in the Societal Challenge health, demographic change and well-being referred to in Regulation (EU) No 1291/2013.
(b) 'direct exploitation' means developing results for commercialization, including through clinical trials, or commercializing results themselves."

- If the subcontracting substantially changes the nature of the project (i.e there is a doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action) the costs will be rejected.

The beneficiary shall specify in this section:

a) the work (the tasks) performed by a subcontractor which may cover only a limited part of the action;
b) explanation of the circumstances which caused the need for a subcontract, taking into account the specific characteristics of the action;
c) the confirmation that the subcontractor has been selected ensuring the best value for money or, if appropriate, the lowest price and avoiding any conflict of interests.

5.2.2 Unforeseen use of in kind contribution from third party against payment or free of charges (if applicable)

Exceptionally, the IMI2 JU may approve costs related to in-kind contributions not included in Annex 1 and 2 without formally amending the GA if the circumstances are explained and justified by the beneficiary in this section.

- The approval is at the discretion of the IMI2 JU, and there is no automatic entitlement to it. Therefore, beneficiaries that do not amend the GA to include third parties, their in-kind contributions and estimated costs in Annex 1 assume the risk of non-approval by the IMI2 JU and rejection of costs.
- Approval will not be granted if the in-kind contribution risks to substantially change the nature of the project (i.e. there is doubt whether the project is still (in substance) the same as the one that was selected or whether the beneficiary has still the operational capacity to carry out the action).

The beneficiary shall specify in this section:

d) the identity of the third party;
e) the resources made available by the third party respectively against payment or free of charges
f) explanation of the circumstances which caused the need for using these resources for carrying out the work;

Annex I - Summary of project outputs

To be submitted as an annual deliverable due with the each periodic report submission.

Please fill the below table for your project. Some sections of the form may not be relevant to your project. The information on your project will provide IMI with statistics and indicators on societal and socio-economic issues addressed by projects. It will help to feed Key Performance Indicators (KPIs) for the measurement of performance and results against strategic overarching priorities identified as critical for overall success of IMI. The replies for individual project will not be made public.

Where appropriate please document the resources produced by the project (with the exclusion of deliverable reports and publications) and where they are archived for the purpose of reproducibility/verifiability. If the resource is destroyed (e.g. biosamples) please indicate.

1. Project general information	
Research area	
Type of impact	*Methodology, model, tool, process, drug etc*
Stage in drug development pathway	*Lead discovery, lead optimisation, Pre-clinical, clinical, manufacturing, etc*

2. Resource Input (background) from the Project Partners				
	Number of resources pooled	**Size**	**Unit** (data, samples subjects, compounds, etc)	**Comments**
Data sets[16]				*Briefly describe resource*
Biobanks[17]				*Briefly describe resource*
Biologicals Samples[18]				*Briefly describe resource*
Cohorts[19]/ Patient registries[20]				*Briefly describe resource*
Software[21]				*Briefly describe resource*
Models, tools				*Briefly describe resource*
Compounds				*Briefly describe resource*
Other (please specify)				*Briefly describe resource*

[16] Any organised collection of data
[17] A collection of biological material and the associated data and information stored in an organised system, for a population or a large subset of a population.
[18] A biological specimen including, for example, blood, tissue, urine, etc. taken from a participant.
[19] A cohort is a group of persons who experience a certain event in a specified period of time. For example, the birth cohort of 1985 would be the people born in that year.
[20] An application which stores metadata for querying, and which can be used by any other application in the network with sufficient access privileges.
[21] Programmes, procedures and data associated with the operation of a computer system.

3. Resource Outputs of the project

Models, tools, technologies, molecules, protocols			
	Number/size and type	**Stage of development**	**Resource location and identifier, future maintenance** Provide unique identifier, DOI, data citation, or reference to publication
Biomarkers	*Type – e.g. efficacy, safety, prognostic, etc*	*Identified, validated, qualified, etc*	
Preclinical models (in vitro)		*Standardised, validated, qualified, etc*	
Preclinical models (in vivo)		*Standardised, validated, qualified, etc*	
In silico models		*Standardised, validated, qualified, etc*	
Tools (diagnostic)/assays		*Standardised, validated, qualified, etc*	
Patient reported outcomes		*Standardised, validated, qualified, etc*	
Modelling and Simulation technologies		*Standardised, validated, qualified, etc*	
New drug targets		*Discovered, validated, qualified, etc*	
Novel hit and lead molecules			
Novel clinical protocols			
New disease related definitions			
Other (specify)			
Infrastructure (operations)			
Patient registries/cohorts	*Number of patients included*		
Clinical Networks	*Number of centres*		
Biobanks	*Number of samples*		
Other (specify)			

'Big data' solutions to leverage knowledge[22]		
	Number/size and type	**Comments / Resource location and identifier, future maintenance** Provide unique identifier, DOI or data citation
Databases	*size*	*Data citation including Data model description, data quality description, interoperability through format and content standards,*
New data collection	*# of studies with new data collection*	*Data Citation*
Harmonization of existing data from multiple sources (pooling)	*# of data fields reviewed and harmonized*	*Data Citation*
Linking different databases (linked data)[23]	*number of data & information sources linked*	*Data Citation*
Software applications	*# deployed /# releases / #newly developed*	*Please specify internal / public. Validated, Data Citation*
Mathematical/Statistical Model Repositories for reuse	*# of models curated and loaded*	*Data Citation*
Other (specify)		
Implementation of Standards		
	Number/size and type	**Comments / Resource location and identifier, future maintenance** **Provide unique identifier, DOI or data citation**
Data Format and Content Standards and Vocabularies (including ontologies)	*adopted/adapted or developed; references*	*Data Citation; In collaboration with a standards development organisation (eg CDISC) Yes/NO* *Have the standards and vocabularies been cited in project publications? Yes/no*
Standard Operating Procedures	*# developed; application area*	*Data Citation; Are the procedures Findable/ Accessible / Reusable)?*
Other (specify)		

[22] Any record which can be used to support a scholarly research argument. The term "data" is meant to be broadly inclusive with the exclusion of digital manifestations of text. Data refers to forms of data and databases that are not self-describing -- that require the assistance of metadata, computational machinery and/or software in order to be useful, such as various types of laboratory data including spectrographic, genomic sequencing, and electron microscopy data; observational data; clinical trial data, assay data; as well as other forms of data either generated or compiled by humans or machines. Source: modified from https://www.force11.org/datacitation

[23] Linking databases maintained by two organisations in different geographical locations, or simply heterogeneous systems within one organisation that, historically, have not easily interoperated at the data level. Source: modified from http://eprints.soton.ac.uk/271285/1/bizer-heath-berners-lee-ijswis-linked-data.pdf

Education and Training Programme outputs		
	Number	**Comments**
Courses conducted		*Training type, face to face or e-course, masters, stand alone, etc*
Trainees who completed continuous professional development training programs		*Trainee type; EFPIA, academia, regulators, patients*
Students graduated from different training programmes		*Trainee type; EFPIA, academia, regulators, patients*
Teachers involved in the training programmes		*Trainee type; EFPIA, academia, regulators, patients*
Training centres labelled “excellence”		
Countries covered by training centres		*List countries*
Other (specify)		
Business related outputs		
	Number	**Comments**
Implementation of project results in industry		*Brief description*
Patents or other IP rights		*Filled, awarded, from what countries and what type of institution (academia, industry, SME, etc.)*
Spin offs created or planned		*Name, partners involved, etc*
Buy outs, take overs		*Partners involved, etc*
Licencing deals		*Type of deal and partners involved*
Commercialisation	*Number of products released to the market*	*Brief description*
Number of additional EFPIA companies and funding attracted (after GA signature)		*List entities and funding leveraged*
Number of additional beneficiaries attracted (after GA signature)		*List entities*
Additional funding sources and amounts		
Other (specify)		
Impact on regulatory framework		
Regulators part of the consortium	*Yes or no*	*List entities*
Regulators part of advisory board	*Yes or no*	*List entities*
Qualification advice completed or in progress	*Yes or no*	*Comments*
Qualification opinion completed or in progress	*Yes or no*	*Comments*
Input into regulatory practices	*Yes or no*	*Details*
Impact on Health Technology Assessment framework		
HTA bodies part of the consortium	*Yes or no*	*List entities*
HTA bodies part of advisory board	*Yes or no*	*List entities*
HTA opinion completed or in progress	*Yes or no*	*Comments*
Input into HTA practices	*Yes or no*	*Comments*
Sustainability plans		
Sustainability/business plan in place (yes/no)	*Brief description*	

4. Stakeholder engagement		
SMEs	**Number**	**Comments**
SMEs as consortium partners		*Type of SME; research, management, etc*
SMEs created		*Size of company created and type*
SME growth		*Staff hires, opening new sites*
Patient organisations	**Number**	**Comments**
Participation to the consortium		*List entities*
Participation to the advisory/ethics board		*List entities*
Consultations at hoc		*List entities*
Engagement with healthcare professionals	**Number**	**Comments**
Participation to the consortium		*List entities*
Participation to the advisory board		*List entities*
Consultations at hoc		*List entities*

5. Collaboration		
	Number	**Comments**
Memoranda of Understanding within IMI		*List collaborators*
Memoranda of Understanding outside IMI		*List collaborators*
Staff exchanges and internships		*Type; industrial and academic internship*

6. Dissemination		
	Number	**Comments**
Publications		*How many were open access*
Data citation		
External newsletter circulated		
Presentations at scientific meetings		*Type of meeting, audience type, size and country*
Website for general public (patients)		
Press releases		
Media (TV, radio, press, multimedia)		*Type of media outlet and target audience*
Brochures / posters / flyers		*Type of target audience*