Periodic technical report – Part B

Project[1] 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*]*

[1] 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[2].

(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.

[2]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[3], 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.

[3] 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[4]				*Briefly describe resource*
Biobanks[5]				*Briefly describe resource*
Biologicals Samples[6]				*Briefly describe resource*
Cohorts[7]/ Patient registries[8]				*Briefly describe resource*
Software[9]				*Briefly describe resource*
Models, tools				*Briefly describe resource*
Compounds				*Briefly describe resource*
Other (please specify)				*Briefly describe resource*

[4]Any organised collection of data
[5]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.
[6] A biological specimen including, for example, blood, tissue, urine, etc. taken from a participant.
[7]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.
[8]An application which stores metadata for querying, and which can be used by any other application in the network with sufficient access privileges.
[9]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[10]		
	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)[11]	*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)		

[10]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

[11]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*