



Periodic project report Inhaled Antibiotics in Bronchiectasis and Cystic Fibrosis iABC

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Period 08/2017 – 07/2018

Reporting Period 3

Description of work - DoW v2.0

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Declaration of the coordinator

I, the coordinator of this project, declare that,

The periodic report submitted is in line with the obligations as stated in Article II.2.3 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 deviations¹;
- has failed to achieve critical objectives and/or is not at all on schedule²

The public project website www.iabcproject.com 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 (section 6) and if applicable with the certificate on financial statement.

All participants, in particular non-profit public bodies, secondary and higher education establishments, research organisations and SMEs, have declared to have verified their legal status. Any changes or deviations have been reported under section 5 (Project Management) in accordance with Article II.3.f of the Grant Agreement.

Name of the Coordinator:

Date:/...../.....

Signature of the Coordinator:

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David

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¹ If either of these boxes is ticked, the report should reflect these and any remedial actions taken

² If either of these boxes is ticked, the report should reflect these and any remedial actions taken

1 Executive summary

Project rationale and overall objectives of the project

The iABC (inhaled Antibiotics in Bronchiectasis and Cystic Fibrosis) consortium brings together world leading researchers to develop new antibiotic treatment options for people with CF and BE by sharing expertise and resources. It involves 20 partners in 7 countries, 2 pharmaceutical EFPIA member companies and four pan-European networks: ECFS-CTN, EMBARC, COMBACTE CLIN-Net and COMBACTE LAB-Net. These groups combine experience with proven expertise and success in (i) antibiotic development (ii) designing and successfully leading randomized clinical trials in cystic fibrosis (CF) and bronchiectasis (BE) (iii) high-quality research on the epidemiology, detection and treatment of chronic respiratory infection in CF and BE (iv) establishing and running a data registry and clinical trials network (v) endpoint analysis. Methodological expertise includes formulation, clinical and molecular microbiology, toxicology, clinical epidemiology, PK/PD and DMPK. Their existing infrastructure provides an excellent basis for the successful achievement of the objectives of ND4BB Topic 7 IMI JU 11th call to develop novel inhaled antibiotic regimens in patients with CF and BE. This will address a critical bottleneck in the development of antimicrobial agents for the treatment of chronic lung infection caused by *Pseudomonas aeruginosa* (Pa) and other Gram-negative non-fermenters (GnNFs).

The Description of Work (DoW) contains activities to deliver the objectives outlined below

1. To determine the therapeutic efficacy of Tobramycin inhaled powder (TIP) in BE patients
2. To explore novel endpoints (microbiome, LCI and CT imaging) for clinical trials in both CF and BE
3. To build repositories of clinical respiratory isolates and sputum biobanks for use in future research
4. To develop an EU-wide prospective registry of BE in all EU and EU-associated countries to facilitate better clinical care and future research into this disease.
5. Study the formulation of Murepavadin (POL7080) in a preclinical setting to support the clinical development of inhaled therapy in patients with CF
6. Establish the pharmacology, DMPK and non-clinical safety of POL7080
7. Support the clinical development of inhaled POL7080 against respiratory infections with *Pseudomonas aeruginosa* (including multidrug resistant) in patients with CF.

Overall deliverables of the project

To achieve the objectives, the programme has been subdivided into 6 WPs each with specific deliverables which are summarised below:

- WP1 implements the management structure to handle the administrative, legal and financial aspects of the project
- WP4 supports the clinical development of TIP for patients with BE. Three studies of the efficacy and safety of tobramycin in BE patients with a history of exacerbations and chronic Pa infection will be performed: a Phase II dose finding study followed by a Phase III confirmatory programme.
- WP5 will develop an EU-wide registry for BE and aim to provide comprehensive data on the epidemiology, natural history and management of BE in Europe.
- WP6 will define new and clinically relevant exploratory endpoints which can be used in clinical trials assessing the efficacy of antimicrobials and other therapeutic agents in CF and BE. Exploratory endpoints studied will include microbiome analysis, LCI, sputum inflammatory biomarkers and chest CT imaging. In addition, quantitative sputum microbiology will be performed to determine changes in sputum density/resistance of Pa and other pathogens in clinical studies where relevant.
- WP7 supports the pre-clinical development of Murepavadin (POL7080) as an inhalation therapy.

- WP8 supports the clinical development of Murepavadin (POL7080) for use in patients with Cystic Fibrosis (clinical studies). A Phase 1 study of POL7080 in CF patients will be performed to determine a tolerable dose and generate safety, pharmacology and first efficacy data.

Summary of progress versus plan since last period

This is the third periodic report of the iABC consortium and progress has continued. In Q4 2017, IMI accepted a project amendment request presented by the consortium. The amendment requested the addition of two new partners, Polyphor Ltd and Vall d'Hebron Research Institute (VHIR) and the addition of two new work packages WP7 and WP8 to the work plan. The new plan is now fully operational and has reinvigorated the project. In addition, WP5 has continued to build on the tremendous success in establishing the EU registry. Patient registration at the end of this period stands at 106 with funding secured for a number of years beyond the life of this project. This body of information is also attracting keen academic interest. The Novartis sponsored Phase II inhaled TIP study in WP4, iBEST1, continues to recruit with over 50% of the planned patient number enrolled. Recruitment was slower than initially planned, but recent actions taken in conjunction with the delivery partner have begun to bear fruit. WP6 laboratory activity has increased as more patients are recruited to iBEST-1 study and work on defining novel exploratory end-points, including the Lung Clearance Index (LCI) sub-study and Computerised Tomography (CT) scanning continues. Polyphor, who joined the consortium in August 2017, have integrated well and are making a positive contribution with an ambitious programme of work. In WP7 they have begun to develop an inhaled version of POL7080 (Murepavadin) with pre-clinical testing underway. Work has also advanced in WP8 on the design of Phase 1 trials for Murepavadin planned for the next period. The consortium continues to work well as a team as focus now shifts toward the mid-project evaluation and consolidated planning on the use of remaining resources.

Significant achievements since last report

Key achievements this period include:-

- The EU Bronchiectasis registry has to date recruited over 14,265 patients in 33 countries, providing an invaluable resource for academic and clinicians. 3 papers have been delivered, directly acknowledging EMBARC/iABC along with 27 abstracts across 4 international respiratory conferences. 2 conference sessions have also been dedicated to presentation and discussion of the registry.
- The iBEST-1 Phase II clinical study has continued to recruit patients. 48 sites have been initiated in 7 countries. Recruitment has been ongoing since Feb 2017. As of 20 September 2018 104 patients have been enrolled.
- The Polyphor team, since joining the consortium in August 2017, are contributing positively and their WP7 pre-clinical testing programme for the Polyphor IMP POL7080 has been quickly established.
- POL7080 susceptibility testing (conventional and biofilm) against *P. aeruginosa* strains from cystic fibrosis patients has provided results that have supported the decision to proceed to pre-clinical inhalation toxicology studies for which an EU tender has been released.
- Design of the inhaled Murepavadin Phase 1 clinical studies are at an advanced stage
- Development and testing of standardized protocols for DNA extraction, PCR, NGS and CT scanning
- Development and delivery of LCI Training programme, eLearning tool (www.MBWtraining.com) and a central LCI reading service in QUB.
- Development and use of a central laboratory microbiology manual in the Phase II iBEST-1 study.

2 Summary of progress against objectives

2.1 Summary table

Work - Package	Milestone/ Deliverable (number and short title)	Date Due (Annex I- description of work)	Completed (Yes/Not yet/Partially)	Dissemin. level ¹	Related document attached (Yes/No/Not applicable)
4	D4.2 Phase II trial of TIP in BE patients (abbreviated report of key outcomes).	M39	Not yet – planned M54	N/A	Not applicable
6	D6.4 NGS microbiome analysis of samples collected in Phase II TIP dose finding study and comparison of exploratory molecular and conventional microbiological endpoints.	M35	Not yet	N/A	Not applicable
6	D6.9 Interim analysis (Phase II TIP dose finding study) of the responsiveness of LCI endpoint in comparison to conventional FEV1 endpoint and CT parameters.	M35	Not yet	N/A	Not applicable
6	D6.11 Final Analysis of Phase II TIP CT outcome measures: Cross sectional and longitudinal comparison of CT related outcome measures to spirometry and LCI outcome measures.	M35	Not yet	N/A	Not applicable
6	D6.15 Analysis of sputum inflammatory biomarker data collected in Phase	M35	Not yet	N/A	Not applicable

¹ PU = Public, fully open, e.g. web CO = Confidential, restricted under conditions set out in Model Grant Agreement CI = Classified, information as referred to in Commission Decision 2001/844/EC.

	2 TIP dose finding study and comparison with conventional and other exploratory endpoints				
6	M6.1 Exploratory molecular endpoints to measure changes in composition of the airway microbiome/resistome determined.	M35	Not yet	N/A	Not applicable
6	M6.5 Validation of LCI as a meaningful secondary exploratory outcome measure in Phase II TIP BE study (WP 4B).	M35	Not yet	N/A	Not applicable
6	M6.7 Websites for standardization of chest CTs in Phase II and III studies.	M35	Not yet	N/A	Not applicable
6	M6.9 Exploratory sputum inflammatory biomarker endpoints determined	M35	Not yet	N/A	Not applicable
7	M7.1 Preliminary report the optimal conditions for nebulization of POL7080 as an inhalation therapeutic, with an adequate nebulization device. Decision on whether to proceed to actual development and to inhalation toxicology.	M36	Yes	CO, may be public at a later stage	No Report in M38
7	M7.5.1 In vitro microbiological testing of POL7080 activity against Pa from CF and BE patients completed.	M36	Partially	PU Publication to follow	No Report in M42
7	M7.5.2 MICs and MBCs raw data available to establish adequate dosage in animal model.	M34	Yes	PU Publication to follow	No Report in M42
7	M7.6.2 Calgary biofilm susceptibility raw data available to establish	M34	Yes	PU Publication to follow	No Full report in M54

	adequate dosage in animal model.				
2	D2.7 Biofilm model development and assessment of results	M15	Yes	PU	No Publication added to the task deliverable on SOFIA
6	D6.7 Selected sites involved in LCI measurement for BE Phase II study set up and trained	M7	Partially In total, 27 sites to take part in LCI sub study. (19 sites receiving new devices and 8 sites with existing devices). Training programme and eLearning tool developed. www.MBWtraining.com Training delivered to 20 sites. 13/20 (65%) have completed certification with a mean (range) time since training of 6 (4-14) months. Certification for 6/20 sites is on-going. One site dropped out (no equipment space).	PU	Not applicable
4	M4.5 Completion of enrolment in Phase II trial of TIP	M27	Not yet – planned M38	N/A	Not applicable
4	M4.6 Last patient last visit in the Phase II trial of TIP	M33	Not yet – planned M44	N/A	Not applicable
6	M6.7 Website for standardization of chest CTs in Phase II and Phase III studies	M6+M35	Partially. Testing has been done. Implementation of functionalities until October 2018, then a pilot phase will start. Live Q4 2018.	PU. Website will be open to visit for everyone but a personal account is necessary for access to study information	Not applicable

6	M6.8 BE scoring baseline CTs: Image analysis baseline Phase II (Bauman and Hartmann scoring, PRAGMA-BE)	M8-18, M33, M57	Not yet Currently transfer of CTs to Erasmus MC is in progress. To date 51 complete CT scans received.	CO	Not applicable
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The following activity has also taken place where no deliverables/milestones were foreseen for this period.

Work package 5

The total enrolment in the EMBARC registry was foreseen as 10,000 patients, however the success of this work package has been such that enrolment continues and the current patient count is 14,265. There are 27502 unique records with nearly 80% eligible for year 1 follow up recording and greater than 60% eligible for year 2 follow up

Work package 6

The work package 6 scientific activities continued to gather momentum throughout this period in line with iBEST1.

Sputum microbiology and susceptibility testing: Academic partners at Antwerp and QUB developed a central laboratory microbiology manual which is being used in the Phase II TIP iBEST-1 study. To date, Antwerp have processed 1307 samples and of these 1137 have been sputum samples with 170 swabs processed. Sample aliquots (n=4685) have been sent to Belfast for microbiome and inflammatory biomarker analysis with multiple aliquots from some samples. *P. aeruginosa* isolates (n=614) have been cultured from sputum (n=604) and swabs (n=10) with 116 additional BE pathogens detected from 58 patients. These were: *S. aureus*, n=55; *A. xylosoxidans*, n=22; *H. influenzae*, n=14; *S. maltophilia*, n=10; *S. pneumoniae*, n=7; *Klebsiella spp.*, n=4; *M. catarrhalis*, n=2; *Proteus spp.*, n=2. Antimicrobial susceptibility of tobramycin and other antibiotics has been determined for 524 *P. aeruginosa* isolates.

Molecular analyses as exploratory endpoints to measure changes in composition of the airway microbiome and resistome: Standardized protocols have been developed for DNA extraction, PCR and next-generation sequencing (NGS). Initial experiments comparing qPCR vs. quantitative culture for *P. aeruginosa* in pure culture demonstrated a good correlation. Using excess expectorated sputum samples collected from adult CF patients, total bacterial and *P. aeruginosa* load in CF sputum has also been compared using qPCR and quantitative culture with a good correlation observed. CF sputum samples were also analysed by NGS to enable comparison between relative abundance of *P. aeruginosa* and *P. aeruginosa* load measured by qPCR and culture. The qPCR assay has been used to determine both total bacterial and *P. aeruginosa* load in a large biobank of sputum samples (>1000) collected in previous clinical studies; these samples have already been analysed by NGS and we are currently determining if there is a correlation between *P. aeruginosa* load and relative abundance. Four hundred and sixty-eight samples have been received from Antwerp: 398 sputum samples and 70 swab samples. Two hundred and twenty-seven sputum samples have been processed with protocols currently being adapted for DNA extraction from swabs. Seventy eight samples have been sequenced and data analysed but not linked with patient identifiers.

2.2 Description of progress for delayed milestones/deliverables not yet completed or partially completed

Work Package 4

We reported last period that the Phase II bronchiectasis study (iBEST-1 study) was considerably behind schedule due mainly to sub optimal site engagement and start-up activity by our CRO partner. The study has gained momentum and has continued to recruit patients throughout period 3 however the activity has taken longer than initially anticipated due to a number of unforeseen factors. A significant number of eligible patients were already being treated in line with ERS guidelines. Screen-failure rates were also higher than anticipated (45% vs 31% estimated) mainly due to Pa detection locally and safety exclusion criteria particularly with regard to renal values and impaired hearing. Many sites have exhausted their pool of eligible patients. The consortium have worked consistently with the CRO partner throughout the period to address operational issues and actively improve the recruitment rates. The measures implemented included:

- Setting up a working team between the project team and CRO senior management to stimulate existing sites and explore new opportunities including an escalation plan to improve the vendor performance. This team meets fortnightly
- Increased engagement between TSC members and clinical sites to carry out training and facilitate best practice sharing of successful sites
- Releasing a substantial amendment of the protocol on 09th Feb 2018. The main areas of change were
 - Exclusion criteria
 - Study conduct (re-screening window, discontinuation criteria and renal alert criteria)
 - PK sampling
 - Clarifications
- Exploring the possibility of opening new sites within existing countries and also expanding the trial into further countries.

As this report is submitted, there are plans to add at least 30 new sites. 20 sites in existing countries have been selected and are in various stages of the trial set up process. Regulatory submission and site selections are underway in Latvia and Poland. In addition, the consortium have asked the CRO to carry out feasibility assessments in Portugal, Serbia and Israel.

Work package 6

D6.7: Selected sites involved in LCI measurement for BE Phase II study set up and trained

Of the 20 sites that completed training, 12/20 (60%) were MBW naive. 13/20 (65%) completed certification with a mean (range) time since training of 6 (4-14) months. Certification for 6/20 sites is on-going with a mean (range) time since training of 10 (3-17) months. One site dropped out (no equipment space).

Delayed LCI certification can result in missed LCI data points for randomised patients in sites who have already been initiated. In order to avoid this, LCI data (for certification) from initiated sites are prioritised for analysis and feedback. Follow up, support, re-fresher training and troubleshooting are offered by Belfast over reading centre.

M6.7: Website for standardization of chest CTs in Phase II study:

The requirements for the interactive website have resulted in a more complex structure than was anticipated. To ensure a safe, high quality and site- and study specific environment, a standard web building program was

not suitable. Erasmus MC has contracted a company to construct a functional and overall design. For the Phase III study the website will be essential for standardizing the CT scanning protocols. The website will be ready well in advance of the start of the Phase III study. EMC started testing the website in Q3 2017 but we run into many queries. A new contract is being proposed from Erasmus MC to external party and warrants deadlines for finalisation of the website. In this contract we will set an ultimate deadline in order to deliver the website in November and to have the website live for public in December 2018. In addition a backup plan will be developed in case the company will not meet its deadlines.

Work package 7

M7.5.1: All MIC data is available at the time of this report but smaller tests (mutant prevention concentration, MIC with additives) will follow in the coming months. The report date (M42) will not be altered for the moment.

2.3 Deviations from Description of Work

The majority of work activity continued as per the Description of Work (v2.0) throughout this period. The deviations, as previously described in this report, occurred in WP4 where it was necessary to make changes to the agreed plan in order to improve recruitment rates to the iBEST1 clinical trial. Out of 48 sites initiated, only 36 have actively recruited, due to the scarcity of the patient population. Screen-failure rates were higher than anticipated (45% vs 31% estimated) mainly due to *Pseudomonas aeruginosa* detection locally, safety exclusion criteria (renal values, impaired hearing); several sites have exhausted their pool of eligible patients (*Pseudomonas aeruginosa* presence or lack of pulmonary exacerbation documentation) and a significant proportion of eligible patients already being treated in line with the ERS guidelines with inhaled antibiotics. It was therefore proposed in April 2018 to increase the number of clinical trial sites from 49 to a proposed 71 and the number of countries included from 8 to 10. The result of this expansion is a change in the planned dates for this work package. The dates affected include both the ongoing Phase II trial and the planned subsequent Phase III trial. These changes, including the expansion of the study to increase in number of countries and clinical sites will require reallocation of funding, the amount of which is being discussed with the CRO currently. The most significant consequence of this Phase II iBEST1 study delay is the knock-on effect on the planned Phase III study. This study will also be affected by changes in regulatory landscape so the consortium have begun to discuss how the work plan of the final two years of the project might look with a view to presenting some proposals to IMI JU at the project mid-point review. The adjusted activity plan and the associated budget reconfiguration will be submitted to IMI JU in an amendment anticipated in the next period.

WP6 which provides scientific support to the WP4 clinical trials and has planned deliverables in terms of novel outcomes has been similarly affected by the delay in iBEST1 and the potential changes to the Phase III trial so delivery dates will need to be adjusted accordingly and will form part of the next amendment .

Update August 31st 2018

On 31 August 2018, the worldwide rights to commercialize TOBI Podhaler® (tobramycin inhalation powder) have been acquired by Mylan. As Novartis no longer owns TOBI Podhaler®, the recruitment of new patients into the ongoing Phase IIB CTBM100G2202 study iBEST-1 is being closed. WP4B Trial Steering Committee and consortium partner have been informed. All patients who signed Informed Consent and entered Screening, will continue through to their last scheduled visit. All relevant data from the study will be analysed and shared as per iABC publication plan and Novartis data disclosure policy.

As consequence, the milestone M4.6 (Last patient last visit in the Phase II trial of TIP) is now shifted to M44 (March 2019) and D4.2 (Phase II trial of TIP in BE patients - report of key outcomes-) to M53 (December 2019). All subsequent milestones and deliverables related to Phase-III are also terminated. These changes will be reflected in a request to IMI for an amendment to the grant agreement as soon as the consortium have agreed a way forward.

3 Summary of Major Achievements and key dissemination activities

3.1 Major achievements

This report reflects another period of great change within the iABC consortium and it's Description of Work. IMI JU granted approval for amendment #1 which was submitted in August 2017. This paved the way for Polyphor Ltd to join the consortium and begin the work to develop an inhaled version of Murepavadin (POL7080) alongside the existing work packages. Despite this period of change, the consortium are pleased to report that valuable progress continued to be made. The following are the highlights of the period.

- The EU Bronchiectasis registry has to date recruited 14,265 patients in 33 countries, providing an invaluable resource for academic and clinicians. 3 papers have been delivered, directly acknowledging EMBARC/iABC along with 27 abstracts across 4 international respiratory conferences. 2 conference sessions have also been dedicated to presentation and discussion of the registry.
- The iBEST-1 Phase II clinical study has continued to recruit patients. 48 sites have been initiated in 7 countries. Recruitment has been ongoing since Feb 2017. As of 20 September 2018 104 patients have been enrolled and plans have been put in place to complete recruitment by the end of Q1 2019. A Data Monitoring Committee meeting held 21-Aug 2018 recommended to continue the study without modification; they asked for some clarification on protocol deviations
- The Polyphor team, since joining the consortium in August 2017, are contributing positively and their WP7 pre-clinical testing programme for the Polyphor IMP POL7080 has been quickly established. Biofilm and formulation work have been completed and have provided encouraging results. An EU tender has been released for upcoming toxicology testing which is expected to begin in Q1 2019
- Design of the inhaled Murepavadin Phase 1 clinical studies are at an advanced stage.
- Publication of the article "Use of Calgary and microfluidic BioFlux systems to test the activity of fosfomycin and tobramycin alone and in combination against cystic fibrosis *Pseudomonas aeruginosa* biofilms." in the peer reviewed journal Antimicrobial Agents and Chemotherapy
- POL7080 susceptibility testing (conventional and biofilm) against *P. aeruginosa* strains from cystic fibrosis patients has provided results that have supported the decision to proceed to pre-clinical inhalation toxicology studies
- Development and testing of standardized protocols for DNA extraction, PCR, NGS and CT scanning
- Development and delivery of LCI Training programme, eLearning tool (www.MBWtraining.com) and a central LCI reading service in QUB
- Development and use of a central laboratory microbiology manual in the Phase II iBEST-1 study

3.2 Key dissemination activities

Nature of Communication	Title	Responsible Participant (and presenter when relevant)	Date/location when relevant.	Target audience
Abstract presentation	Antimicrobial susceptibility against a collection of <i>pseudomonas aeruginosa</i> recovered from cystic fibrosis and bronchiectasis patients	Maria Diaz Aguilar. SERMAS - HURYC	ECCMID Paris April 2018	Clinical microbiologists
Publication	Use of Calgary and Microfluidic BioFlux Systems To Test the Activity of Fosfomycin and Tobramycin Alone and in Combination against Cystic Fibrosis <i>Pseudomonas aeruginosa</i> Biofilms	Maria Diaz Aguilar. Rafael Canton. SERMAS. Miquel Ekkelenkamp UMCU	December 2017 American Society for Microbiology. Antimicrobial Agents and Chemotherapy	Clinical microbiologists, ID specialists, pneumologists
Poster presentation	A randomised placebo-controlled dose finding study of tobramycin inhalation powder (TIP) in patients with bronchiectasis (BE) and pulmonary <i>P. aeruginosa</i> (Pa) infection	Michael Loebinger and Gerhild Angyalosi	17-Sep 2018 ERS, Paris	Scientific community, patients organisations
Abstract presentation	In vitro antimicrobial activity of tobramycin, colistin, aztreonam and the new antibiotic POL7080 against cystic fibrosis <i>Pseudomonas aeruginosa</i> biofilms	Maria Diez Aguilar SERMAS-HURYC	IMI 10 th anniversary scientific symposium. October 2018, Brussels	IMI researchers
Publication	Patient participation in ERS guidelines and research projects: the EMBARC experience	James Chalmers	Sept 2017 Breathe	Scientific community, patients organisations
Publication	Cross-infection risk in patients with bronchiectasis: a position statement from the European Bronchiectasis Network (EMBARC), EMBARC/ELF patient advisory group and European Reference Network (ERN-Lung) Bronchiectasis Network	James Chalmers, Stuart Elborn, Felix Ringshausen, Charles Haworth, Eva Polverino	European Respiratory Journal. January 11 2018	Scientific community, patients organisations
Poster discussion abstract	How to diagnose and quantify bronchiectasis for clinical studies using chest imaging	H. Tiddens. Presenter: J.J. Meerburg	ERS conference 16 September 2018	Scientific community

Oral presentation of poster	Training in Multiple Breath Washout (MBW) testing for bronchiectasis (BE) clinical trials.	Katherine O'Neill	15-09-2017	European Respiratory Society, 2017
Oral presentation of poster	Multiple Breath Washout (MBW) training, certification and quality control during the iBEST-1 trial in bronchiectasis (BE).	Katherine O'Neill	18-09-2018	European Respiratory Society, 2018

Papers are ongoing in the following areas and publication is planned in P4

- G2202 (iBEST1) study design publication by Novartis

3.3 Use and dissemination of foreground

The results from WP7 susceptibility testing will be published in peer-reviewed journals, likely in year 4 of the project.

Analysis of Whole Genome Sequencing data will be published in peer-reviewed journals, likely in multiple publications in years 3-6 of the project.

Biofilm results are being published in peer-reviewed journals

Animal model results will be published in peer-reviewed journals, over the course of the project.

4 Management of Project and Consortium

4.1 Overall management of the project

The management of the project continued in the same vein as period 2 with strong collaboration among the consortium. The introduction of Polyphor and Vall D'Hebron Institut de Recerca has been a positive force.

An amendment to the Grant Agreement and a new Project Agreement were both signed at the beginning of this reporting period allowing all work package teams to recommence activity.

Throughout the year, the Coordination Unit continued to meet twice each month and the Management Board once per month. Each of the work packages continued their meetings as appropriate and attendance and enthusiasm in all forums remains high.

The annual General Assembly has been delayed to coincide with the European Respiratory Society congress which will be held in Paris in September. At this year's meeting we plan to review the status of each work package and the progress made this year but also discuss proposed work plans for Years 4, 5 and 6 make preparations for the project mid-point review which will take place in Q4 2018.

The iABC project continues to be represented at the ND4BB meetings and the interaction with other members of this group in conjunction with EFPIA has proven invaluable in terms of information exchange. Connections with EMBARC, ERS and ECFS also remain strong.

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

All comments and recommendations highlighted in the P2 report have been noted by the consortium and addressed where necessary. The process of updating previous deliverables into the new template format is complete

4.3 Project plan for the remaining reporting periods

P4 will continue to follow the project plan outlined in Description of Work v2.0.

WP1 will focus on reporting current progress and future plans to both IMI and external reviewers in Q4 2018. It is then anticipated that a request for an amendment will be submitted to IMI JU in Q2 2019. This amendment will reflect the outcome of currently ongoing programme design discussions for P5 and P6.

The **WP4** clinical trial will continue to recruit patients with a view to achieving the milestones and deliverables planned for P3 in Q2/ Q3 2019.

WP5 will continue to recruit patients while producing further analysis of the valuable information collected in the registry.

WP6 in line with WP4 will support the iBEST1 trial and work towards completion of the milestones and deliverables planned for P3 in the coming year.

WP7 Pre-clinical toxicology of the inhaled formulation will be performed in rodents and non-human primates. The definitive formulation and inhalation device will be selected for the clinical studies. The feasibility of dry powder inhalation of murepavadin will be studied. The animal model of CF and the biofilm model will be developed further. Analysis of the Whole Genome Sequencing data will be performed.

At this moment WP7 continues to track the project plan timelines, but delay is expected over the course of the next year. We are getting advance warning that availability of laboratory animals and testing capacity at contract research organizations is limited and preclinical toxicology of murepavadin will therefore not start in the third quarter of 2018, but in the first quarter of 2019. This delay will consequently may impact the timelines of the clinical studies in WP8.

WP8 Clinical trial design will be finalised and preparations for CRO tender will begin

Del. No.	Deliverable name	WP No.	Nature	Delivery date
D4.2	Phase II trial of TIP in BE patients (abbreviated report of outcomes)	4	R	M39
D5.4	Annual data reports.	5	R	M13, M25, M37, M49, M60, M77
D5.5	Peer reviewed publications and abstracts.	5	R	M13, M25, M37, M49, M60, M77
D6.4	NGS microbiome analysis of samples collected in Phase II TIP dose finding study and comparison of	6	R	M33

D6.6	Determination of the composition of the healthy airway microbiome/resistome and how these change/recover following antimicrobial treatment	6	R	M42
D6.9	Interim analysis (Phase II TIP dose finding study) of the responsiveness of LCI endpoint in comparison to conventional FEV ₁ endpoint and CT parameters.	6	R	M33
D6.11	Final Analysis of Phase II TIP CT outcome measures: Cross sectional and longitudinal comparison of CT related outcome measures to spirometry and LCI outcome measures.	6	R	M35
D6.13	Automated measurements of airway-artery dimensions for BE patients	6	R	M42
D6.15	Analysis of sputum inflammatory biomarker data collected in Phase II TIP dose finding study and comparison with conventional and other exploratory endpoints	6	R	M35
D7.1	Report on the development of POL7080 as a nebulized formulation for inhalation therapy	7	R	M38
D7.3	POL7080 in-vitro microbiological testing results	7	R	M42
Milestone No.	Milestone name	WPs involved	Expected delivery date	Means of verification
M4.5	Completion of enrolment in Phase II trial of TIP	4	M38	CRO report received
M4.6	Last Patient last visit in the Phase II TIP study	4	M44	CRO report received
M5.5	Enrolment of 6000 patients from at least 20 EU Countries.	5	M38	Registry data reports
M6.1	Exploratory molecular endpoints to measure changes in composition of the airway microbiome/resistome determined.	6	M35	Abstracts at scientific conferences and journal article
M6.5	Validation of LCI as a meaningful secondary exploratory outcome	6	M35	Abstracts at scientific conferences and journal

	measure in Phase II TIP BE study (WP 4B).			article
M6.7	Websites for standardization of chest CTs in Phase II and III studies.	6	M35	Functional websites, abstracts at scientific conferences and journal articles
M6.8	BE Scoring baseline CTs: Image analysis baseline Phase II (Bauman and Hartmann scoring, PRAGMA-BE). Manual AA and AWA analysis of subset. Prototype 1.1 automated AA and AWA analysis . BE Scoring baseline CTs Phase III at inclusion. Image analysis baseline and follow up CTs Phase III (Bauman or Hartmann scoring , Manual AA and AWA analysis in subset (n=50), prototype 2.1 automated AA + AWA analysis).	6	M33	Abstracts at scientific conferences and journal article
M6.9	Exploratory sputum inflammatory biomarker endpoints determined	6	M35	Abstracts at scientific conferences and journal article
M7.5	In vivo efficacy testing of POL7080 activity against CF P. aeruginosa isolates in acute infection models completed	7	M42	D7.5
M7.7	Development of the β ENaC-Tg mouse model of chronic pulmonary infection and the use of this model for efficacy testing	7	M42	D7.7

Update 31st August 2018

The deliverables and milestones planned for this period as per the DoW are listed above. However, the recent announcement of the sale of the Novartis asset TOBI Podhaler® will necessitate a significant project re-planning exercise. The consortium are likely to request an amendment to the Grant Agreement in the next reporting period which will affect many of these deliverables.

4.4 Risk assessment, when appropriate

Please fill-in the table outlining key risks identified for the upcoming reporting periods and related mitigation plan. Please take into account in your risk assessment the continued relevance of the objectives and breakthrough potential.

Project Risk / Issue	Probability VH/H/M/ L	Impact VH/H/M/ L	Mitigation plan	Responsible Participant	Action to be taken	Due Date
WP7 Potential delay in toxicology testing due to shortage of required primates	H	H	Close collaboration between partners and careful management of the project plan and supplier	POL/UMCU	UMCU to issue tender notice and situation to be carefully monitored	Ongoing
WP8 Potential delay in clinical trial dates due to pre-clinical testing delays	M	H	Close collaboration between partners and careful management of the project plan. Trial design to be examined in line with remaining times	POL/QUB/INS ERM	Bi-weekly project meetings to progress	Ongoing
WP1 Further Change of partnership	L	VH	Effective communication with affected partners to allow action plans to be put in place	All consortium partners	As per above	ongoing
WP4 iBEST-1 Study planned dates slippage	VH	H	Close collaboration between the CRO, trial steering committee and trial sites	NVS/QUB/PA P/RBHT/UNIV DUN/UMIL/F CRB/UEDIN	Weekly meetings with CRO.TSC monitoring closely and taking actions. Decision taken to increase number of sites and countries	ongoing
WP4 iBEST-1 study going over budget	VH	H	Close scrutiny of CRO costs with timely actions being taken.	QUB/NVS	New task orders to be instigated with	ongoing

					spending caps	
WP4 Phase-III study budget	VH	H	Redesign of Y4,5,6 of the project in light of Phase II outcome and remaining budget	QUB/NVS	Consortium meetings underway regarding project outputs. To be discussed with IMI at mid-project review	M40
M6.7 CT website development	M	L	The website will not be used in phase II study so therefore it will not affect this study	Prof H Tiddens	New contract proposal: delivery website Nov 2018, website live for public Dec 2018.	Q4 2018
M6.8 CT	M	L	Dependent on inclusion last patient and on the participating hospitals that have to send EMC the CT-scans. As soon as EMC have received all scans EMC can start the analysis. EMC proposes to start the analysis 3 months after LPFV regardless the number of collected CT scans to prevent delay.	Prof H Tiddens		15 months after LPFV
Added after Novartis announcement 31st August 2018						
WP4B iBEST-1 clinical significance of an underpowered study	V	M	Close collaboration with CRO and sites to maximize data quality	NVS/QUB/PA P/RBHT/UNI VDUN/UMIL/FCRB/JEDIN	Close collaboration with CRO, weekly monitoring of activities, TSC actively engaged	ongoing

VH = Very High, H = High, M = Medium, L = Low

5 Finance – Cost

5.1 Cost summary

- Reporting of costs incurred by IMI beneficiaries and third parties

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Participant 3; Novartis Pharma AG (NOV) – [PY3]			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
...	Personnel direct costs	1'453'426.44	<ul style="list-style-type: none"> • 6.95 FTE (= 83.42 PM) • WP1: Novartis representatives in iABC governance (coordination Unit, Management Board and SCOC) • WP4B: Co-lead and Trial management of iABC iBEST-1 Phase-2 study including preparation of all study related material (protocol and related documents), management of CRO start-up activities, regulatory activities (DRA Hub), Supply testing and management • WP6: Co-leader and support to all activities linked to Bronchiectasis Phase-2 study
	Subcontracting [if foreseen in Description of Work]	346'361.63	WP4B: Ongoing contracts with 4 vendors on iBEST-1 Phase-2 study
	Other direct costs		
	Consumables [if applicable]	278'382.18	WP4B: Consumables i.e. Tobramycin Inhaled Powder clinical supply
	Equipment depreciation	0	
	Other	0	
	Indirect costs		
	Sub-total in kind contribution	2'078'170.25	
	Direct financial contribution	539'953.67	WP1, WP4 & WP6: QUB (Queen's University Belfast)
	Total in kind contribution	2'618'123.92	
	Of which Non-EU in kind contribution²	1'056'239.67	WP 4B: Novartis clinical and technical team members located in East Hanover (NJ, USA), Hyderabad (India) and San Carlos (CA, USA)
	Budget for the period		
	Deviation		.

² when there is a special clause 13 in the Grant Agreement

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Participant 3; Novartis Pharma AG (NOV) – Period 1 (PY1)			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
WPs: 1, 4B & 6	Personnel direct costs (fully loaded FTE costs)	+163'686.33	0.8 fully loaded FTEs (=9.64 PMs) engaged in: <ul style="list-style-type: none"> • WP4b: Additional activities linked to consumables supply for trial medication
WPs: 4B	Subcontracting [if foreseen in Description of Work]	+156'819.69	WP4b: Additional work to test design of inhaler for elderly patients
WPs: 4B	Consumables [if foreseen in Description of Work]	+306'459.46	WP4B: Consumables i.e. Tobramycin Inhaled Powder clinical supply not included in original Y1 reporting, now added.
Sub-total in kind contribution		626'965.48	
Direct financial contribution		+66'913.00	Correction of assignment of quarterly payment
Total in kind contribution		693'878.48	
Of which Non-EU in kind contribution³		+544'960.61	Resulting from above adjustments
Budget for the period			n.a.
Deviation			

³ when there is a special clause 13 in the Grant Agreement

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Participant 3; Novartis Pharma AG (NOV) – Period 2 (PY2)			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
WPs: 1, 4B, 5& 6	Personnel direct costs (fully loaded FTE costs)	+44358.73	0.23 fully loaded FTEs (=2.75 PMs) engaged in: <ul style="list-style-type: none"> • WP4B: Additional activities linked to consumables supply for trial medication
WPs: 4B	Subcontracting [if foreseen in Description of Work]	-332.35	Correction of cost allocation
WPs: 4B	Consumables [if foreseen in Description of Work]	+113479.37	WP4B: Consumables i.e. Tobramycin Inhaled Powder clinical supply not included in original Y2 reporting, now added.
	Sub-total in kind contribution	157'505.75	
	Direct financial contribution		
	Total in kind contribution	157'505.75	
	Of which Non-EU in kind contribution⁴	+131533.45	Resulting from above adjustments
	Budget for the period		n.a.
	Deviation		

⁴ when there is a special clause 13 in the Grant Agreement

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Participant 2: Queen's University, Belfast (QUB)

Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
1; 4; 6; 7	Personnel direct costs	324,541.55	50.37PM RTD – 3 Academics, 3 Postdoc researchers, 2 technician 30.41PM Management - 2 project managers, clinical coordinator, 2 academic
4	Subcontracting [if foreseen in Description of Work]	1,651,895.36	CRO – ICON tender as per DoA Audit cert
	Other direct costs		
4;6; 7	Consumables [if applicable]	75,999.93	Misc consumables
6	Equipment depreciation [if applicable]	228,478.12	depreciation of important equipment LCI machines purchased for clinical sites YR 1, 2 and 3 depreciation;
4;6; 7	Other [if applicable]	27,739.11	Travel €27,133.02, Hospitality €606.09
	Indirect costs	131,351.68	e.g. 20% flat rate, actual indirect costs
TOTAL COSTS		2,441,118.06	
Budget for the period		£0	
Deviation		£0	

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Participant 4: Universitair Medisch Centrum Utrecht UMCU			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
4	Personnel direct costs	€ 63.481	<i>Salary costs for 1Scientist/Lead Investigator</i>
	Subcontracting <i>[if foreseen in Description of Work]</i>	€ 0	
	Other direct costs	€ 1.242	<i>Travel costs to iABC meetings in Basel and General assembly Paris and general Assembly in Milan</i>
	<i>Consumables [if applicable]</i>	€ 50.730	<i>Costs incurred for whole genome sequencing.</i>
	<i>Equipment depreciation [if applicable]</i>	€ 0	<i>depreciation of important equipment (provide detail)</i>
	<i>Other [if applicable]</i>		<i>e.g. maintenance of the web site , animal costs</i>
	Indirect costs	€ 23.090,60	<i>20% flat rate</i>
TOTAL COSTS		€ 138.543,60	
Budget for the period		€ 106.633,50	
Deviation		€ 31.910,10	

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Participant 5 – Belfast Health & Social Care Trust (BHSCT)			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
...	Personnel direct costs	0	e.g. salaries of 2 postdoctoral students
	Subcontracting [if foreseen in Description of Work]		
	Other direct costs		
	Consumables [if applicable]		
	Equipment depreciation [if applicable]		depreciation of important equipment (provide detail)
	Other [if applicable]		e.g. maintenance of the web site , animal costs
	Indirect costs		e.g. 20% flat rate, actual indirect costs
TOTAL COSTS		€0	
Budget for the period		€0	
Deviation		€0	

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Participant 7: UNIVERSITY OF GRONINGEN (RUG)			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
7	Personnel direct costs	5.159,20	Salary postdoc 1 pm
7		50.232,00	
7		40.133,16	Salary technician 6 pm
7		46.191,60	Salary professor 3,4 pm Salary phd 12 pm
	Subcontracting [if foreseen in Description of Work]		
	Other direct costs		
	Consumables [if applicable]		
7	Equipment depreciation [if applicable]	4347,17	Loop-12 months depreciation a 362,3 = 4347,17: ((Amount 19200, date invoice 29-3-2016, total depreciation months 53, this period 12)
7	Equipment depreciation [if applicable]	1300,75	Dehumidifier-12 months depreciation a 108,40 = 1300,75: ((Amount 5745, date invoice 29-3-2016, total depreciation months 53, this period 12)
7	Equipment depreciation [if applicable]	10329,82	Demo Discovery TGA-12 months depreciation a 860,8 = 10329,82: ((Amount 47345, date invoice 18-1-2016, total depreciation months 55, this period 12)
7	Equipment depreciation [if applicable]	4470,83	Inhaler 12 months depreciation a 372,6 = 4470,83: ((Amount 21609, date invoice 30-10-2015, total depreciation months 58, this period 12)
7	Other [if applicable]	1198,75	Lab chemicals
7	Other	3164,44	Lab supplies
7	Other	0	Travel costs Basel 6-6-2016/7-6-2016 meeting IABC
	Indirect costs	33.305,54	
TOTAL COSTS		199.833,26	
Budget for the period		151.171	
Deviation		48.662,26	More personnel costs needed

**TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING
PERIOD 3: FROM 01/08/2017 TO 31/07/2018**

Partner 8 – Servicio Madrileño de Salud (SERMAS)			
Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources
WP7	Personnel direct costs	58990.12 €	<i>PM (Hired personnel cost: María Díez (35746.52 € = 11 PM) + Own-Staff Personnel cost; R.Cantón, MI. Morosini, M.Tato (23243.60€ = 4,11 PM)</i>
	Subcontracting <i>[if foreseen in Description of Work]</i>		
	Other direct costs	2396.84 €	
WP7	<i>Consumables [if applicable]</i>	372 €	<i>Reagent –Tobramycin sulfate salt aminoglycoside (372 €)</i>
WP7	<i>Travel</i>	1003.98 €	<i>1) Attendance of Rafael Cantón and María Díez Aguilar to the iABC WP7 REVIEW AND PLANNING MEETING. (Allschwill, Switzerland. 13/03/18) FLIGHT MADRID-MILAN (278€). Hotel (338 €), Taxi ticket & Madrid airport toll, Hotel city Tax (67, 98€). 2) Attendance of Rafael Cantón and María Díez Aguilar to i-ABC-GA ANNUAL MEETING. (Paris, Francia) - 19th September, 2018 (320 €).</i>
	<i>Equipment depreciation [if applicable]</i>		
WP1	<i>Management</i>	1020.86 €	<i>Dissemination costs: 1) Maria Díez Aguilar. 28TH ESCMID Congress. 21-24 April 2018, Madrid (Spain). Registration costs (175€) 2) Article publication - ASM-AAC01650-17 (806.66€) 3) Poster printout 28TH ESCMID Congress 21-24 April 2018, Madrid (Spain) – (39.2€)</i>
	Indirect costs	12277.39 €	e.g. 20% flat rate, actual indirect costs
TOTAL COSTS		73664.35 €	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING
P3: ADJUSTMENT PERIOD 1: FROM 01/08/2015 TO 31/07/2016

Partner 8 – Servicio Madrileño de Salud (SERMAS)			
Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources
WP2	Personnel direct costs	641.05 €	<i>We have made a second Adjustment of the P1 report due to the fact that, in P1 we have calculated the total salary cost without sum the Gross salary + prorated extra salary. The description of the costs remains the same: WP2: 2.2 person-months (1 pm of SERMAS Principal Investigator + 1.2 pm of two researchers of the SERMAS team (staff of the hospital))</i>
	Subcontracting <i>[if foreseen in Description of Work]</i>		
	Other direct costs	0.00 €	
	<i>Consumables [if applicable]</i>		
	<i>Travel</i>		
	Equipment depreciation <i>[if applicable]</i>		
	Hardware/Software/licence costs		
	Indirect costs	128.21 €	e.g. 20% flat rate, actual indirect costs
TOTAL COSTS		769.26 €	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING
P3: ADJUSTMENT PERIOD 2: FROM 01/08/2016 TO 31/07/2017

Partner 8 – Servicio Madrileño de Salud (SERMAS)			
Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources
WP2	Personnel direct costs	707.61 €	<i>We have made an Adjustment of the P2 report due to the fact that, in P2 we have calculated the total salary cost without sum the Gross salary + prorated extra salary. The description of the costs remains the same: WP2: 2.3 person-months (Researchers of the SERMAS team (staff of the hospital)).</i>
	Subcontracting <i>[if foreseen in Description of Work]</i>		
	Other direct costs	0.00 €	
	<i>Consumables [if applicable]</i>		
	<i>Travel</i>		
	<i>Equipment depreciation [if applicable]</i>		
	<i>Hardware/Software/licence costs</i>		
	Indirect costs	141.52 €	<i>e.g. 20% flat rate, actual indirect costs</i>
TOTAL COSTS		849.13 €	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Participant 9 – Universitair Ziekenhuis Antwerpen [UZA]			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
WP6	Personnel direct costs	80793.22	Salaries of 3 junior lab personnel 16.2 PM 1 senior lab personnel 1.3 PM lab director for mgt of this project 0.7 PM
	Subcontracting [if foreseen in Description of Work]		
	Other direct costs		
WP6	Consumables [if applicable]	19639.39	Lab consumables
WP6	Equipment depreciation [if applicable]	3284.97	Depreciation 5 years of -80°C freezer This has been calculated according to the local depreciation rules
WP6	Other [if applicable]	14559.15	ICT consumables – support package 14500 euro Meeting costs 59.15 euro
	Indirect costs	23655.34	20% flat rate
TOTAL COSTS		141932.07	
Budget for the period		292134.60	
Deviation		-150202.53	

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Participant 10 University of Dundee (UNIVDUN)			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
5	Personnel direct costs	€100364.47	<i>Megan Crichton, Research Assistant, 10.36PM. James Chalmers, Principle Investigator, 0.51PM RTD, 0.01pm Management Leandro Tramma, Database Coordinator, 4.76PM. Keith Milburn, Database Coordinator, 0.84PM. Gayle Scott, Project Manager 3.29PM. Samantha Thomson, Clerical Assistant, 3.70PM.</i>
5	Subcontracting [if foreseen in Description of Work]	144876.98	<i>Payments for enrolment of patients to study sites</i>
	Other direct costs		
5	<i>Consumables [if applicable]</i>	702.15	<i>Graphpad Prism perpetual academic Q, 100ml reagent troughs (pk 100), freight charge</i>
	<i>Equipment depreciation [if applicable]</i>	0.00	<i>depreciation of important equipment (provide detail)</i>
5	<i>Other [if applicable]</i>	150.50	<i>Attendance at WTCRF Course in Edinburgh. Teleconference call for EMBARC</i>
N/A	<i>Travel</i>	8248.25	<i>World Bronchiectasis Conference, Milan – Meeting between US and European Registries. External expert from South Africa for meeting on international registries</i>
		1511.76	<i>European Respiratory Society Conference, 8-13 Sept 2017 – attendance at EMBARC registry meetings</i>
			<i>World Bronchiectasis Conference, Washington – Attendance and presenting registry data at EMBARC registry meetings 10-16/7/18</i>
			<i>American Thoracic Society meeting, June 2017 – Presenting registry data</i>
	<i>Audit costs</i>		<i>Audit costs</i>
	Indirect costs	22195.42	<i>20% flat rate, except subcontracting</i>
TOTAL COSTS		278049.53	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Participant 11 Institut National De La Sante Et De La Recherche Medicale (INSERM)			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
...	Personnel direct costs	0	e.g. salaries of 2 postdoctoral students
	Subcontracting <i>[if foreseen in Description of Work]</i>		
	Other direct costs		
	<i>Consumables [if applicable]</i>		
	<i>Equipment depreciation [if applicable]</i>		<i>depreciation of important equipment (provide detail)</i>
	<i>Other [if applicable]</i>		<i>e.g. maintenance of the web site , animal costs</i>
	Indirect costs		<i>e.g. 20% flat rate, actual indirect costs</i>
TOTAL COSTS		€0	
Budget for the period		€0	
Deviation		€0	

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Participant 1101 Université de Poitiers (UP)			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
...	Personnel direct costs	0	e.g. salaries of 2 postdoctoral students
	Subcontracting [if foreseen in Description of Work]		
	Other direct costs		
	Consumables [if applicable]		
	Equipment depreciation [if applicable]		depreciation of important equipment (provide detail)
	Other [if applicable]		e.g. maintenance of the web site , animal costs
	Indirect costs		e.g. 20% flat rate, actual indirect costs
TOTAL COSTS		€0	
Budget for the period		€0	
Deviation		€0	

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Participant 12 – <i>Università degli Studi di Milano - UMIL</i>			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
4; 1	Personnel direct costs	€ 35,208.82	1.34 M/M effort of Prof. Francesco Blasi: <ul style="list-style-type: none"> • 0.96 M/M for activities related to WP4 • 0.38 M/M for activities related to WP1 10 M/M effort of Dr. Martina Oriano for activities related to WP4
	Subcontracting [if foreseen in Description of Work]		
	Other direct costs	€ 920.34	Costs for travel and subsistence for project meetings In detail: <ol style="list-style-type: none"> 1. Travel and subsistence cost reimbursement to Dr. Oriano for participation to the meeting in Scotland (€ 339.81) 2. Travel cost reimbursement to Prof. Blasi for participation to the meeting in Brussels (€ 580.53)
	Consumables [if applicable]		
	Equipment depreciation [if applicable]		
	Other [if applicable]		
	Indirect costs	€ 7,041.76	20% flat rate
TOTAL COSTS		€ 43,170.92	
Budget for the period			
Deviation			No significant deviation has to be signalled. Prof. Blasi supervised the development of activities foreseen for UMIL. A post-doc position (Dr. Martina Oriano) started in October 2017 as foreseen.

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Third Party beneficiary 1201 : Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
4	Personnel direct costs		<i>Salary costs for 1 Scientist/Lead Investigator</i>
	Subcontracting <i>[if foreseen in Description of Work]</i>		
	Other direct costs	13.908,48	<i>4 patients full procedure (€ 3.477,12 each)</i>
		562,09	<i>1 patient screening V1 (€ 562,09)</i>
	<i>Consumables [if applicable]</i>		
	<i>Equipment depreciation [if applicable]</i>		<i>depreciation of important equipment (provide detail)</i>
	<i>Other [if applicable]</i>		<i>e.g. maintenance of the web site , animal costs</i>
	Indirect costs	2.894,11	<i>20% flat rate</i>
TOTAL COSTS		17.364,68	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Participant 13 Hospices Civils de Lyon (HCL)			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
...	Personnel direct costs	0	e.g salaries of 2 postdoctoral students
	Subcontracting [if foreseen in Description of Work]		
	Other direct costs		
	Consumables [if applicable]		
	Equipment depreciation [if applicable]		depreciation of important equipment (provide detail)
	Other [if applicable]		e.g. maintenance of the web site , animal costs
	Indirect costs		e.g. 20% flat rate, actual indirect costs
TOTAL COSTS		€0	
Budget for the period		€0	
Deviation		€0	

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Participant 14 Medizinische Hochschule Hannover [MHH] Periode 3			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
WP4	Personnel direct costs	35.538,08 €	<i>Salary costs for 1 Technican, 9 personnel months</i>
	Subcontracting <i>[if foreseen in Description of Work]</i>	0,00	
	Other direct costs	0,00	
WP4	<i>Cardiac examination</i>	50,34 €	
WP8	<i>Travel costs</i>	656,64	
WP4	<i>Expenses allowance to probands</i>	1.032,31 €	
WP4	<i>Laboratory test</i>	823,60 €	
WP4	<i>Material for tests</i>	299,00 €	
	<i>Equipment depreciation [if applicable]</i>	0,00	<i>depreciation of important equipment (provide detail)</i>
	<i>Other [if applicable]</i>	0,00	<i>e.g. maintenance of the web site , animal costs</i>
	Indirect costs	7.679,99 €	<i>20% flat rate</i>
TOTAL COSTS		46.079,97 €	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Participant 14 Medizinische Hochschule Hannover [999878426] Adjustment P2			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
WP4B	Personnel direct costs	3.452,29	2 Technican 0,74 Months,
	Subcontracting <i>[if foreseen in Description of Work]</i>	0,00	
	Other direct costs	0,00	
	<i>Consumables [if applicable]</i>	0,00	
	<i>Equipment depreciation [if applicable]</i>	0,00	<i>depreciation of important equipment (provide detail)</i>
	<i>Hardware/Software/licence costs</i>	0,00	
	Indirect costs	690,46	<i>e.g. 20% flat rate, actual indirect costs</i>
TOTAL COSTS		4.142,75	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Participant 15 Universiteit Antwerpen (UANTWERP)			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
...	Personnel direct costs	0	e.g. salaries of 2 postdoctoral students
	Subcontracting [if foreseen in Description of Work]		
	Other direct costs		
	Consumables [if applicable]		
	Equipment depreciation [if applicable]		depreciation of important equipment (provide detail)
	Other [if applicable]		e.g. maintenance of the web site , animal costs
	Indirect costs		e.g. 20% flat rate, actual indirect costs
TOTAL COSTS		€0	
Budget for the period		€0	
Deviation		€0	

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Participants 16+1601: University of Edinburgh (UEDIN) (with NHS Lothian as 3 rd Party) – Period 3			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
...	Personnel direct costs	17,209.41	Adam Hill, PI, 1.20 PM
	Subcontracting [<i>if foreseen in Description of Work</i>]		
	Other direct costs		
	<i>Consumables [if applicable]</i>		
	<i>Equipment depreciation [if applicable]</i>		
	<i>Other: Travel</i>		
	Indirect costs	3,441.88	20% flat rate
TOTAL COSTS		20,651.29	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Participant 17: Royal Brompton and Harefield Trust (RBHT)			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
	Personnel direct costs	43,512.74	Salary cost for Principal Investigator Dr Michael Loebinger.
	Subcontracting <i>[if foreseen in Description of Work]</i>		
	Other direct costs	2,684.57	Patient travel costs.
	<i>Consumables [if applicable]</i>		
	<i>Equipment depreciation [if applicable]</i>		depreciation of important equipment (provide detail)
	<i>Hardware/Software/licence costs</i>		
	Indirect costs	9,239.46	e.g. 20% flat rate, actual indirect costs
TOTAL COSTS		55,436.77	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Participant no. *Papworth Hospital NHS Foundation Trust*

Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
4	Personnel direct costs	7,659.47	<i>Salary costs for 1 Study Investigator a 1 research nurse</i>
	Subcontracting <i>[if foreseen in Description of Work]</i>		
	Other direct costs	237.97	<i>Travel costs</i>
		8600.00	<i>Patient 002 – study costs</i>
	<i>Consumables [if applicable]</i>		
	<i>Equipment depreciation [if applicable]</i>		<i>depreciation of important equipment (provide detail)</i>
	<i>Other [if applicable]</i>		<i>e.g. maintenance of the web site , animal costs</i>
	Indirect costs		<i>20% flat rate</i>
TOTAL COSTS		16,497.44	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Participant 20 Erasmus Universitair Medisch Centrum Rotterdam (EMC)			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
WP6	Personnel direct costs	€ 124.726,71	<i>PhD student € 58.535,89 (12 PM) Lung Analysis € 27.021,32 (4,56 PM) Research coordinator € 4.317,49 (0,75 PM) PhD student €31.254,85 (8 PM) Associate professor € 3.597,16 (0,33 PM)</i>
	Subcontracting <i>[if foreseen in Description of Work]</i>	€ 29.427,94	<i>3D animation movie € 4.430 Development website € 25.042,94</i>
	Other direct costs	€2.600,09	<i>Travel costs €2.600,09</i>
	<i>Consumables [if applicable]</i>		
	<i>Equipment depreciation [if applicable]</i>		<i>depreciation of important equipment (provide detail)</i>
	<i>Other [if applicable]</i>		<i>e.g. maintenance of the web site , animal costs</i>
	Indirect costs	€ 25.465,36	<i>20% flat rate</i>
TOTAL COSTS		€182.265,10	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Participant 21 Fundació Hospital Universitari Vall d'Hebron – Institut de Recerca (VHIR)			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
4	Personnel direct costs	2.792,08€	<i>Eva Polverino (PI) 1,06PM</i>
4	Personnel direct costs	24.041,75€	<i>Patricia Chang (Technician) 3,19Pm; Carlos Gómez (Technician) 1,87PM; Sónia López (Technician) 4,97PM and Javier Pérez (Pre-doc) 0,55PM In respect of iBEST1 clinical trial</i>
	Subcontracting <i>[if foreseen in Description of Work]</i>		
	Other direct costs		
4	<i>Travel</i>	475.80€	<i>Travel project meeting (18-19/03/2018 London, Eva Polverino) for Phase III clinical trial design meeting</i>
	<i>Equipment depreciation [if applicable]</i>		<i>depreciation of important equipment (provide detail)</i>
	<i>Other [if applicable]</i>		<i>e.g. maintenance of the web site , animal costs</i>
	Indirect costs	5.461,93€	<i>20% flat rate</i>
TOTAL COSTS		32.771,55€	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Participant 21 Fundació Hospital Universitari Vall d'Hebron – Institut de Recerca (VHIR) P2 adjustment

Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
4	Personnel direct costs	2.149,16€	<i>Eva Polverino (PI) 0,81 PM</i>
	Subcontracting <i>[if foreseen in Description of Work]</i>		
	Other direct costs		
	<i>Consumables [if applicable]</i>		
	<i>Equipment depreciation [if applicable]</i>		<i>depreciation of important equipment (provide detail)</i>
	<i>Other [if applicable]</i>		<i>e.g. maintenance of the web site , animal costs</i>
	Indirect costs	429,83€	<i>20% flat rate</i>
TOTAL COSTS		2.579€	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Participant 22; Polyphor Ltd (POL) – Period 1 (PY1)			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
WP: 1, 7, 8	Personnel direct costs	299708.5	1.43 FTEs engaged in: <ul style="list-style-type: none"> • WP 1: Polyphor representatives in iABC governance (Coordination Unit, Management Board) • WP7: Co-lead and support/management of preclinical development work and in vitro and in vivo testing of POL7080 (Murepavadin) including formulation, biofilm and activity studies including preparation of all study related material as well as preparation and management of pre-clinical studies. • WP8: Co-lead and support to activities linked to preparation of Phase-1 study Note: due to delay in start of project less FTEs used
WP: 7	Subcontracting	122759.98	WP7: Contracts with CROs for preclinical studies
WP: 7	Consumables	11140.61	WP 7: Consumables for studies at UMCU, RUG and subcontractors including Murepavadin drug substance
WP: 1, 7	Other	9473.98	WP 7: Travel
	Sub-total in kind contribution	443083.07	
	Direct financial contribution	0	Note: WP1 & WP7 QUB (Queen's University Belfast) – invoice has not been sent/received
	Total in kind contribution	443,083.07	
	Of which Non-EU in kind contribution¹	0	
	Budget for the period	1,330,635	22% of total commitment
	Deviation	887,551.93	[Note: direct contribution not yet included]

6 Form C and Summary Financial Report

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each EFPIA company

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	IABC Programme		

Period from	01/08/2017	Is this an adjustment to a previous statement?	No
To	31/07/2018		

Legal Name	Novartis Pharma AG	Participant Identity Code (PIC)	999754557
Organisation short Name	NOV	Participant nbr	1

Indirect Costs	
Method based on actual indirect costs?	Yes
Method based on flat rate of 20 %?	No

1- Declaration of eligible in kind contribution (in €)

	Amount
Personnel costs	1,453,426.44
Subcontracting	346,361.63
Other direct costs	278,382.18
Indirect costs	0.00
Total	2,078,170.25

2- Declaration of Financial contribution

Did you provide any financial contribution to a beneficiary or to a participant under special clause 11?
 If yes, please name the beneficiary(ies)/participants under special clause 11 to whom you provided a financial contribution
 Please mention the total amount (in €), if you provided a contribution

Yes
QUB (Queens University Belfast)
539,953.67

3- Total In Kind contribution (1 + 2)

Of which in kind contribution for research activities conducted outside a Member State or an associated country, in accordance with special clause 13 a) or b), if one of this special clauses applies

2,618,123.92
1,056,239.67

4- Certificate on the methodology

Do you declare costs based on a certified methodology on in kind contribution according to Art. II.13.4 of the grant agreement?
 Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?
 Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

Yes
No
No

5- Certificate on the financial statements


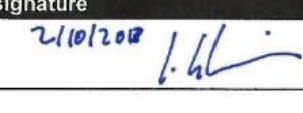
Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those EFPIA companies that declare costs on the basis of a certified methodology in accordance with Art. II.13.4 of the grant agreement, and for those EFPIA companies that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2. of the grant agreement, except for the final reporting period; Art. II.4.5 of the grant agreement.)

Yes

Name of the auditor	PricewaterhouseCoopers AG Switzerland	Cost of the certificate (in €)	3,847.12
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6- EFPIA Company's declaration on its honour

We declare on our honour that:
 - the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 and Article 7 (special clauses) of the grant agreement;
 - there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit.

EFPIA company's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	Vincent Malaterre, Global Program Team Director; Sebastian Schlechtriem, Head Finance Development Respiratory & E
	Date & signature
	 

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each EFPIA company

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	IABC Programme		

Period from	01/08/2015	Is this an adjustment to a previous statement?	Adjustment to period 1
To	31/07/2016		

Legal Name	Novartis Pharma AG	Participant Identity Code (PIC)	999754557
Organisation short Name	NOV	Participant nbr	1

Indirect Costs	
Method based on actual indirect costs?	Yes
Method based on flat rate of 20 %?	No

1- Declaration of eligible in kind contribution (in €)

	Amount
Personnel costs	163,686.33
Subcontracting	156,819.69
Other direct costs	306,459.46
Indirect costs	0.00
Total	626,965.48

2- Declaration of Financial contribution

Did you provide any financial contribution to a beneficiary or to a participant under special clause 11?

Yes

If yes, please name the beneficiary(ies)/participants under special clause 11 to whom you provided a financial contribution

UQB (Universty Queens Belfast)

Please mention the total amount (in €), if you provided a contribution

66,913.00

3- Total In Kind contribution (1 + 2)

Of which in kind contribution for research activities conducted outside a Member State or an associated country, in accordance with special clause 13 a) or b), if one of this special clauses applies

693,878.48

544,960.61

4- Certificate on the methodology

Do you declare costs based on a certified methodology on in kind contribution according to Art. II.13.4 of the grant agreement?

Yes

Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?

No

Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

No

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those EFPIA companies that declare costs on the basis of a certified methodology in accordance with Art. II.13.4 of the grant agreement, and for those EFPIA companies that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2. of the grant agreement, except for the final reporting period; Art. II.4.5 of the grant agreement.)


No

Name of the auditor		Cost of the certificate (in €)	0.00
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6- EFPIA Company's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 and Article 7 (special clauses) of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit.

EFPIA company's Stamp	Name of the Person(s) Authorised to sign this Financial Statement	
	Vincent Malaterre, Global Program Team Director; Sebastian Schlechtriem, Head Finance Development Respiratory & E	
	Date & signature	
	21/10/2018	21/10/2019 

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each EFPIA company

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	IABC Programme		

Period from	01/08/2016	Is this an adjustment to a previous statement?	Adjustment to period 2
To	31/07/2017		

Legal Name	Novartis Pharma AG	Participant Identity Code (PIC)	999754557
Organisation short Name	NOV	Participant nbr	1

Indirect Costs	
Method based on actual indirect costs?	Yes
Method based on flat rate of 20 %?	No

1- Declaration of eligible in kind contribution (in €)

	Amount
Personnel costs	44,358.73
Subcontracting	-332.35
Other direct costs	113,479.37
Indirect costs	0.00
Total	157,505.75

2- Declaration of Financial contribution

Did you provide any financial contribution to a beneficiary or to a participant under special clause 11?
If yes, please name the beneficiary(ies)/participants under special clause 11 to whom you provided a financial contribution
Please mention the total amount (in €), if you provided a contribution

No
0.00

3- Total In Kind contribution (1 + 2)

Of which in kind contribution for research activities conducted outside a Member State or an associated country, in accordance with special clause 13 a) or b), if one of this special clauses applies

157,505.75
131,533.45

4- Certificate on the methodology

Do you declare costs based on a certified methodology on in kind contribution according to Art. II.13.4 of the grant agreement?
Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

Yes
No
No

5- Certificate on the financial statements


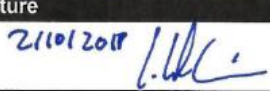
Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those EFPIA companies that declare costs on the basis of a certified methodology in accordance with Art. II.13.4 of the grant agreement, and for those EFPIA companies that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2. of the grant agreement, except for the final reporting period; Art. II.4.5 of the grant agreement.)

No

Name of the auditor		Cost of the certificate (in €)	0.00
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6- EFPIA Company's declaration on its honour

We declare on our honour that:
- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 and Article 7 (special clauses) of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit.

EFPIA company's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	Vincent Malaterre, Global Program Team Director; Sebastian Schlechtriem, Head Finance Development Respiratory & E
	Date & signature
	2/10/2018  2/10/2018 

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	IABC Programme		

Period from	01/08/2017	Is this an adjustment to a previous statement?	No
To	31/07/2018		

Legal Name	The Queen's University of Belfast	Participant Identity Code (PIC)	999992013
Organisation short Name	QUB	Participant number in the project	2

Funding % for RTD activities (A)	75 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	168,252.24	156,289.00	0.00	0.00	324,541.24
Subcontracting	1,651,895.38	1,112.62	0.00	0.00	1,653,007.98
Other direct costs	332,217.16	0.00	0.00	0.00	332,217.16
Sub-total direct costs	2,152,364.78	157,401.62	0.00	0.00	2,309,766.38
Indirect costs	100,093.88	31,257.80	0.00	0.00	131,351.68
Total	2,252,458.64	188,659.42	0.00	0.00	2,441,118.06
Maximum IMI JU contribution	1,689,343.88	188,659.42	0.00	0.00	1,878,003.40
Requested IMI JU contribution					1,878,003.40

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?
If yes, please mention the amount (in €)

Yes
539,953.14

2b) Other receipts
Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. II.16 of the grant agreement?
If yes, please mention the amount (in €)

No
0.00

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. II.18 of the grant agreement?
If yes, please mention the amount (in €)

No
0.00

4- Certificate on the methodology

Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

No
No

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2 of the grant agreement, except for the final reporting period: Art. II.4.5 of the grant agreement.)

Yes
1,275.58

Name of the auditor	KPMG	Cost of the certificate (in €)	1,275.58
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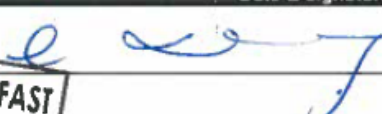
6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. II.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorized representatives.

ONLY FOR THE MANGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. II.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	Aveen Lavery
	Date & signature
	 30/10/18



IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	iABC Programme		
Period from	01/08/2017	Is this an adjustment to a previous statement?	No
To	31/07/2018		
Legal Name	University Medical Center Utrecht	Participant Identity Code (PIC)	999915189
Organisation short Name	UMCU	Participant number in the project	4
Funding % for RTD activities (A)	75 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	54,395.00	9,086.00	0.00	0.00	63,481.00
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	51,972.00	0.00	0.00	0.00	51,972.00
Sub-total direct costs	106,367.00	9,086.00	0.00	0.00	115,453.00
Indirect costs	21,273.40	1,817.20	0.00	0.00	23,090.60
Total	127,640.40	10,903.20	0.00	0.00	138,543.60
Maximum IMI JU contribution	95,730.30	10,903.20	0.00	0.00	106,633.50
Requested IMI JU contribution					106,633.50

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?
If yes, please mention the amount (in €)

2b) Other receipts
Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. 11.16 of the grant agreement?
If yes, please mention the amount (in €)

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. 11.18 of the grant agreement?
If yes, please mention the amount (in €)

4- Certificate on the methodology

Do you declare average personnel costs according to Art. 11.13.2 of the grant agreement?
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. 11.13.2 of the grant agreement?

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. 11.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. 11.13.2. of the grant agreement, except for the final reporting period; Art. 11.4.5 of the grant agreement.)

Name of the auditor

Cost of the certificate (in €)

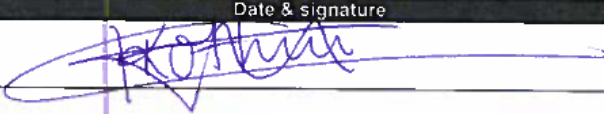
6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. 11.13 and 11.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. 11.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section 11.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANAGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. 11.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	Femke Kothuis
	Date & signature
	

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	IABC Programme		

Period from	01/08/2017	Is this an adjustment to a previous statement?	No
To	31/07/2018		

Legal Name	Belfast Health and Social Care Trust	Participant Identity Code (PIC)	998348930
Organisation short Name	BHSCT	Participant number in the project	5

Funding % for RTD activities (A)	75 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	0.00	0.00	0.00	0.00	0.00
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	0.00	0.00	0.00	0.00	0.00
Sub-total direct costs	0.00	0.00	0.00	0.00	0.00
Indirect costs	0.00	0.00	0.00	0.00	0.00
Total	0.00	0.00	0.00	0.00	0.00
Maximum IMI JU contribution	0.00	0.00	0.00	0.00	0.00
Requested IMI JU contribution					0.00

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?
If yes, please mention the amount (in €)

No
0.00

2b) Other receipts
Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. II.16 of the grant agreement?
If yes, please mention the amount (in €)

No
0.00

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. II.18 of the grant agreement?
If yes, please mention the amount (in €)

No
0.00

4- Certificate on the methodology

Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

No
No

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2 of the grant agreement, except for the final reporting period, Art. II.4.5 of the grant agreement.)

No

Name of the auditor

Cost of the certificate (in €)	0.00
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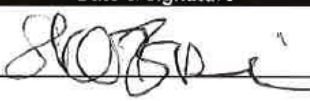
6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. II.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANAGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. II.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
Belfast Health & Social Care Trust	Kate O'Brien
RECEIVED	Date & signature
26 SEP 2018	
RESEARCH	

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr Project Acronym	115721 iABC Programme	Funding scheme	IMI Research Project
Period from To	01/08/2017 31/07/2018	Is this an adjustment to a previous statement?	No
Legal Name Organisation short Name	RIJSUNIVERSITEIT GRONINGEN RUG	Participant Identity Code (PIC) Participant number in the project	99989782 7
Funding % for RTD activities (A)	75 %	Indirect Costs Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	141,715.96	0.00	0.00	0.00	141,715.96
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	24,811.76	0.00	0.00	0.00	24,811.76
Sub-total direct costs	166,527.72	0.00	0.00	0.00	166,527.72
Indirect costs	33,305.64	0.00	0.00	0.00	33,305.64
Total	199,833.26	0.00	0.00	0.00	199,833.26
Maximum IMI JU contribution	149,874.95	0.00	0.00	0.00	149,874.95
Requested IMI JU contribution					149,874.95

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?

If yes, please mention the amount (in €)

No
0.00

2b) Other receipts

Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. II.16 of the grant agreement?

If yes, please mention the amount (in €)

No
0.00

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. II.18 of the grant agreement?

If yes, please mention the amount (in €)

No
0.00

4- Certificate on the methodology

Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?

Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

No
No

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2. of the grant agreement, except for the final reporting period: Art. II.4.5 of the grant agreement.)



No

Name of the auditor		Cost of the certificate (in €)	0.00
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6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
 - the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. II.16 of the grant agreement;
 - there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.
- ONLY FOR THE MANAGING ENTITY
- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. II.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
 university of groningen faculty of science and engineering	A.Ebbes
	Date & signature
	4-9-2018 

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr Project Acronym	115721 IABC Programme	Funding scheme	IMI Research Project
Period from To	01/08/2017 31/07/2018	Is this an adjustment to a previous statement?	No
Legal Name Organisation short Name	SERVICIO MADRILEÑO DE SALUD SERMAS	Participant Identity Code (PIC) Participant number in the project	999481987 8
Funding % for RTD activities (A)	75 %	Indirect Costs Method based on actual indirect costs? Method based on flat rate of 20 %?	No Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	58,990.12	0.00	0.00	0.00	58,990.12
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	1,376.98	1,020.86	0.00	0.00	2,396.84
Sub-total direct costs	60,366.10	1,020.86	0.00	0.00	61,386.96
Indirect costs	12,073.22	204.17	0.00	0.00	12,277.39
Total	72,439.32	1,225.03	0.00	0.00	73,664.35
Maximum IMI JU contribution	54,329.49	1,225.03	0.00	0.00	55,554.52
Requested IMI JU contribution					55,554.52

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?
If yes, please mention the amount (in €)

2b) Other receipts
Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. II.16 of the grant agreement?
If yes, please mention the amount (in €)

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. II.18 of the grant agreement?
If yes, please mention the amount (in €)

4- Certificate on the methodology

Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2. of the grant agreement, except for the final reporting period: Art. II.4.5 of the grant agreement.)

Name of the auditor

Cost of the certificate (in €)


6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. II.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANAGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. II.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	JOSÉ IGNACIO FLORES NICOLÁS
	Date & signature
	27 th August, 2018

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	iABC Programme		

Period from	01/08/2015	Is this an adjustment to a previous statement?	Adjustment to period 1
To	31/07/2016		

Legal Name	SERVICIO MADRILEÑO DE SALUD	Participant Identity Code (PIC)	999481987
Organisation short Name	SERMAS	Participant number in the project	8

Funding % for RTD activities (A)	75 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	641.05	0.00	0.00	0.00	641.05
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	0.00	0.00	0.00	0.00	0.00
Sub-total direct costs	641.05	0.00	0.00	0.00	641.05
Indirect costs	128.21	0.00	0.00	0.00	128.21
Total	769.26	0.00	0.00	0.00	769.26
Maximum IMI JU contribution	576.95	0.00	0.00	0.00	576.95
Requested IMI JU contribution					576.95

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?

If yes, please mention the amount (in €)

No
0.00

2b) Other receipts

Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. 11.16 of the grant agreement?

If yes, please mention the amount (in €)

No
0.00

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. 11.18 of the grant agreement?

If yes, please mention the amount (in €)

No
0.00

4- Certificate on the methodology

Do you declare average personnel costs according to Art. 11.13.2 of the grant agreement?

Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. 11.13.2 of the grant agreement?

No
No

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. 11.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. 11.13.2. of the grant agreement, except for the final reporting period: Art. 11.4.5 of the grant agreement.)


No

Name of the auditor		Cost of the certificate (in €)	0.00
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6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. 11.13 and 11.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
 - the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. 11.16 of the grant agreement;
 - there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives,
- ONLY FOR THE MANAGING ENTITY
- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. 11.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	JOSÉ IGNACIO FLORES NICOLÁS
	Date & signature
	27 th August, 2018

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	IABC Programme		

Period from	01/08/2016	Is this an adjustment to a previous statement?	Adjustment to period 2
To	31/07/2017		

Legal Name	SERVICIO MADRILEÑO DE SALUD	Participant Identity Code (PIC)	999481987
Organisation short Name	SERMAS	Participant number in the project	8

Funding % for RTD activities (A)	75 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	707.61	0.00	0.00	0.00	707.61
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	0.00	0.00	0.00	0.00	0.00
Sub-total direct costs	707.61	0.00	0.00	0.00	707.61
Indirect costs	141.52	0.00	0.00	0.00	141.52
Total	849.13	0.00	0.00	0.00	849.13
Maximum IMI JU contribution	636.85	0.00	0.00	0.00	636.85
Requested IMI JU contribution					636.85

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?

If yes, please mention the amount (in €)

No
0.00

2b) Other receipts

Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. II.16 of the grant agreement?

If yes, please mention the amount (in €)

No
0.00

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. II.18 of the grant agreement?

If yes, please mention the amount (in €)

No
0.00

4- Certificate on the methodology

Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?

Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

No
No

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2. of the grant agreement, except for the final reporting period; Art. II.4.5 of the grant agreement.)


No

Name of the auditor		Cost of the certificate (in €)	0.00
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6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
 - the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. II.16 of the grant agreement;
 - there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.
- ONLY FOR THE MANAGING ENTITY
- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. II.18 of the grant agreement.

	Name of the Person(s) Authorised to sign this Financial Statement
	JOSÉ IGNACIO FLORES NICOLÁS Date & signature 27 th August, 2018

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	iABC Programme		

Period from	01/08/2017	Is this an adjustment to a previous statement?	No
To	31/07/2018		

Legal Name	Universitair Ziekenhuis Antwerpen	Participant Identity Code (PIC)	996727866
Organisation short Name	UZA	Participant number in the project	9

Funding % for RTD activities (A)	75 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	59,127.71	21,665.51	0.00	0.00	80,793.22
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	37,483.51	0.00	0.00	0.00	37,483.51
Sub-total direct costs	96,611.22	21,665.51	0.00	0.00	118,276.73
Indirect costs	19,322.24	4,333.10	0.00	0.00	23,655.34
Total	115,933.46	25,998.61	0.00	0.00	141,932.07
Maximum IMI JU contribution	86,950.10	25,998.61	0.00	0.00	112,948.71
Requested IMI JU contribution					112,948.71

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company? If yes, please mention the amount (in €)	No 0.00
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2b) Other receipts Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. II.16 of the grant agreement? If yes, please mention the amount (in €)	No 0.00
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3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. II.18 of the grant agreement? If yes, please mention the amount (in €)	No 0.00
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4- Certificate on the methodology

Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?	No
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?	No

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2. of the grant agreement, except for the final reporting period: Art. II.4.5 of the grant agreement.)	No
Name of the auditor	Cost of the certificate (in €)
	0.00

6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. II.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. II.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
Universitair Ziekenhuis Antwerpen KLINISCHE BIOLOGIE Wilrijkstraat 10 2650 EDEGEM	Daisy Van Mieghem
	Date & signature

16/09/2018

[Handwritten signature]
100 Tim Cleys

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	IABC Programme		
Period from	01/08/2017	Is this an adjustment to a previous statement?	No
To	31/07/2018		
Legal Name	University of Dundee	Participant Identity Code (PIC)	999975523
Organisation short Name	UNIVDUN	Participant number in the project	10
Funding % for RTD activities (A)	75 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	100,296.90	67.57	0.00	0.00	100,364.47
Subcontracting	144,876.98	0.00	0.00	0.00	144,876.98
Other direct costs	10,612.67	0.00	0.00	0.00	10,612.67
Sub-total direct costs	255,786.55	67.57	0.00	0.00	255,854.12
Indirect costs	22,181.91	13.51	0.00	0.00	22,195.42
Total	277,968.46	81.08	0.00	0.00	278,049.54
Maximum IMI JU contribution	208,476.35	81.08	0.00	0.00	208,557.43
Requested IMI JU contribution					208,557.43

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?

If yes, please mention the amount (in €)

No

0.00

2b) Other receipts

Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. 11.16 of the grant agreement?

If yes, please mention the amount (in €)

No

0.00

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. 11.18 of the grant agreement?

If yes, please mention the amount (in €)

No

0.00

4- Certificate on the methodology

Do you declare average personnel costs according to Art. 11.13.2 of the grant agreement?

Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. 11.13.2 of the grant agreement?

No

No

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. 11.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. 11.13.2 of the grant agreement, except for the final reporting period; Art. 11.4.5 of the grant agreement)

No

Name of the auditor

Cost of the certificate (in €)

0.00

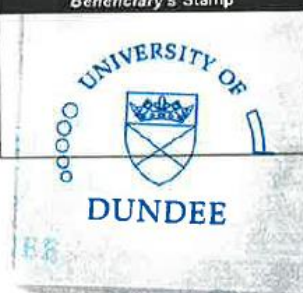
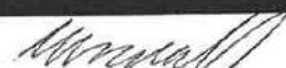
6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. 11.13 and 11.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. 11.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section 11.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANAGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. 11.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	Michael Hassall
	Date & signature
	 27/9/2018

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	IABC Programme		

Period from	01/08/2017	Is this an adjustment to a previous statement?	No
To	31/07/2018		

Legal Name	Institut National de la Santé et de la Recherche Médicale	Participant Identity Code (PIC)	999997833
Organisation short Name	INSERM	Participant number in the project	11

Funding % for RTD activities (A)	75 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	0.00	0.00	0.00	0.00	0.00
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	0.00	0.00	0.00	0.00	0.00
Sub-total direct costs	0.00	0.00	0.00	0.00	0.00
Indirect costs	0.00	0.00	0.00	0.00	0.00
Total	0.00	0.00	0.00	0.00	0.00
Maximum IMI JU contribution	0.00	0.00	0.00	0.00	0.00
Requested IMI JU contribution					0.00

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?
If yes, please mention the amount (in €)

2b) Other receipts
Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. II.16 of the grant agreement?
If yes, please mention the amount (in €)

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. II.18 of the grant agreement?
If yes, please mention the amount (in €)

4- Certificate on the methodology

Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2 of the grant agreement, except for the final reporting period, Art. II.4.5 of the grant agreement.)

Name of the auditor

Cost of the certificate (in €)

6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. II.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. II.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	Richard SALIVES
	Date & signature
	Par délégation
	Karine Gionnet

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by third party
Only applicable if special clause 4 "Third parties linked to a participant" is used
 Not to be filled in by a third party linked to a managing entity (special clause 9) who must use the form for beneficiaries

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	iABC Programme		

Period from	01/08/2017	Is this an adjustment to a previous statement?	No
To	31/07/2018		

Third party legal Name	Université de Poitiers	Working for and linked to beneficiary nr	11
3rd party Organisation short Name	UP		

Funding % for RTD activities (A)	75 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	0.00	0.00	0.00	0.00	0.00
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	0.00	0.00	0.00	0.00	0.00
Sub-total direct costs	0.00	0.00	0.00	0.00	0.00
Indirect costs	0.00	0.00	0.00	0.00	0.00
Total	0.00	0.00	0.00	0.00	0.00
Maximum IMI JU contribution	0.00	0.00	0.00	0.00	0.00
Requested IMI JU contribution					0.00

2- Declaration of receipts

Did you receive any financial transfers or contributions in kind, free of charge from third parties or did the project generate any income which could be considered a receipt according to Art. 11.16 of the grant agreement?
 If yes, please mention the amount (in €)

No
0.00

3- Certificate on the methodology

Do you declare average personnel costs according to Art. 11.13.2 of the grant agreement?
 Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. 11.13.2 of the grant agreement?

No
No

4- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. 11.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those third parties linked to a beneficiary that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. 11.13.2. of the grant agreement, except for the final reporting period: Art. 11.4.5 of the grant agreement.)

No

Name of the auditor		Cost of the certificate (in €)	0.00
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5- Third party's declaration on its honour

We declare on our honour that:
 - the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. 11.13 and 11.14 and Article 7 (special clauses) of the grant agreement;
 - the receipts declared above are the only financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. 11.16 of the grant agreement;
 - there is full supporting documentation to justify the information hereby declared, it will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cf section 11.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

Third party's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	Laurent ANNE Gilles MIRAMBEAU Date & signature 28.8.18 DIRECTEUR GÉNÉRAL DES SERVICES Gilles MIRAMBEAU

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr Project Acronym	116721 IABC Programme	Funding scheme	IMI Research Project
Period from To	01/08/2017 31/07/2018	Is this an adjustment to a previous statement?	No
Legal Name Organisation short Name	Università degli Studi di Milano UMIL	Participant Identity Code (PIC) Participant number in the project	999995796 12
Funding % for RTD activities (A)	75 %	Indirect Costs Method based on actual indirect costs? Method based on flat rate of 20 %?	No Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	31,860.29	3,348.53	0.00	0.00	35,208.82
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	920.34	0.00	0.00	0.00	920.34
Sub-total direct costs	32,780.63	3,348.53	0.00	0.00	36,129.16
Indirect costs	6,556.13	669.71	0.00	0.00	7,225.84
Total	39,336.76	4,018.24	0.00	0.00	43,355.00
Maximum IMI JU contribution	29,502.57	4,018.24	0.00	0.00	33,520.81
Requested IMI JU contribution					33,520.81

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?

If yes, please mention the amount (in €)

No
0.00

2b) Other receipts

Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. II.16 of the grant agreement?

If yes, please mention the amount (in €)

No
0.00

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. II.18 of the grant agreement?

If yes, please mention the amount (in €)

No
0.00

4- Certificate on the methodology

Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?

Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

No
No

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2 of the grant agreement, except for the final reporting period: Art. II.4.5 of the grant agreement.)

No

Name of the auditor		Cost of the certificate (in €)	0.00
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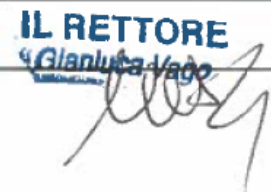
6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. II.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANAGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. II.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	Gianluca Gaetano Vago
	Date & signature
	02 AGO. 2018 

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by third party
 Only applicable if special clause 4 "Third parties linked to a participant" is used
 Not to be filled in by a third party linked to a managing entity (special clause 9) who must use the form for beneficiaries

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	iABC Programme		
Period from	01/08/2017	Is this an adjustment to a previous statement?	No
To	31/07/2018		
Third party legal Name	FONDAZIONE IRCCS CA' GRANDA OSPEDALE MAGGIORE POLICLINICO		
3rd party Organisation short Name	IRCCS CA' GRANDA	Working for and linked to beneficiary nr	12
Funding % for RTD activities (A)	75 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	0.00	0.00	0.00	0.00	0.00
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	14,470.57	0.00	0.00	0.00	14,470.57
Sub-total direct costs	14,470.57	0.00	0.00	0.00	14,470.57
Indirect costs	2,894.11	0.00	0.00	0.00	2,894.11
Total	17,364.68	0.00	0.00	0.00	17,364.68
Maximum IMI JU contribution	13,023.51	0.00	0.00	0.00	13,023.51
Requested IMI JU contribution					13,023.51

2- Declaration of receipts

Did you receive any financial transfers or contributions in kind, free of charge from third parties or did the project generate any income which could be considered a receipt according to Art. II.16 of the grant agreement?
 If yes, please mention the amount (in €)

No
0.00

3- Certificate on the methodology

Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?
 Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

No
No

4- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those third parties linked to a beneficiary that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2. of the grant agreement, except for the final reporting period; Art. II.4.5 of the grant agreement.)

No

Name of the auditor	Cost of the certificate (in €)
	0.00

5- Third party's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. II.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

Third party's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
FONDAZIONE IRCCS CA' GRANDA OSPEDALE MAGGIORE POLICLINICO Via F. Sforza, 28 20122 MILANO	dr Simona Giroidi
	Date & signature 24 SET. 2018

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	iABC Programme		
Period from	01/08/2017	Is this an adjustment to a previous statement?	No
To	31/07/2018		
Legal Name	Hospices Civils de Lyon (Lyon General Hospitals)	Participant Identity Code (PIC)	999469765
Organisation short Name	HCL	Participant number in the project	13
Funding % for RTD activities (A)	75 %	Indirect Costs Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	0.00	0.00	0.00	0.00	0.00
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	0.00	0.00	0.00	0.00	0.00
Sub-total direct costs	0.00	0.00	0.00	0.00	0.00
Indirect costs	0.00	0.00	0.00	0.00	0.00
Total	0.00	0.00	0.00	0.00	0.00
Maximum IMI JU contribution	0.00	0.00	0.00	0.00	0.00
Requested IMI JU contribution					0.00

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?
If yes, please mention the amount (in €)

No
0.00

2b) Other receipts
Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. 11.16 of the grant agreement?
If yes, please mention the amount (in €)

No
0.00

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. 11.18 of the grant agreement?
If yes, please mention the amount (in €)

No
0.00

4- Certificate on the methodology

Do you declare average personnel costs according to Art. 11.13.2 of the grant agreement?
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. 11.13.2 of the grant agreement?

No
No

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. 11.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. 11.13.2. of the grant agreement, except for the final reporting period Art. 11.4.5 of the grant agreement.)

No

Name of the auditor

Cost of the certificate (in €)

0.00



6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. 11.13 and 11.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. 11.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section 11.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANAGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. 11.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement	
	Mrs Anne METZINGER	
	Date & signature	
	2/08/2018	

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr Project Acronym	115721 IABC Programme	Funding scheme	IMI Research Project
Period from To	01/08/2017 31/07/2018	Is this an adjustment to a previous statement?	No
Legal Name Organisation short Name	MEDIZINISCHE HOCHSCHULE HANNOVER MHH	Participant Identity Code (PIC) Participant number in the project	999878426 14
Funding % for RTD activities (A)	75 %	Indirect Costs Method based on actual indirect costs? Method based on flat rate of 20 %?	No Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	35,538.08	0.00	0.00	0.00	35,538.08
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	2,861.89	0.00	0.00	0.00	2,861.89
Sub-total direct costs	38,399.97	0.00	0.00	0.00	38,399.97
Indirect costs	7,879.99	0.00	0.00	0.00	7,679.99
Total	46,079.96	0.00	0.00	0.00	46,079.96
Maximum IMI JU contribution	34,559.97	0.00	0.00	0.00	34,559.97
Requested IMI JU contribution					34,559.97

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?

If yes, please mention the amount (in €)

No
0.00

2b) Other receipts

Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. II.16 of the grant agreement?

If yes, please mention the amount (in €)

No
0.00**3- Declaration of interest yielded by the pre-financing** (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. II.18 of the grant agreement?

If yes, please mention the amount (in €)

No
0.00**4- Certificate on the methodology**

Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?

Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

No
No**5- Certificate on the financial statements**

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2. of the grant agreement, except for the final reporting period. Art. II.4.5 of the grant agreement.)

No

Name of the auditor

Cost of the certificate (in €)

0.00


6- Beneficiary's declaration on its honour


We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. II.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable, (cf section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANAGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. II.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement	
	I.A. David Göbel	
	Date & signature	
	 14-SEP-2018	
	Medizinische Hochschule Hannover Zentrum Innere Medizin Klinik für Pneumologie Prof. Dr. med. T. Weite Carl-Neuberg-Straße 1 • 30625 Hannover	Medizinische Hochschule Hannover Drittmittelabteilung Carl-Neuberg-Straße 1 • 30625 Hannover


 17.09.2018

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr Project Acronym	116721 iABC Programme	Funding scheme	IMI Research Project
Period from To	01/08/2016 31/07/2017	Is this an adjustment to a previous statement?	Adjustment to period 2
Legal Name Organisation short Name	MEDIZINISCHE HOCHSCHULE HANNOVER MHH	Participant Identity Code (PIC) Participant number in the project	999878426 14
Funding % for RTD activities (A)	75 %	Indirect Costs Method based on actual indirect costs? Method based on flat rate of 20 %?	No Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	3,452.29	0.00	0.00	0.00	3,452.29
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other-direct costs	0.00	0.00	0.00	0.00	0.00
Sub-total direct costs	3,452.29	0.00	0.00	0.00	3,452.29
Indirect costs	690.46	0.00	0.00	0.00	690.46
Total	4,142.75	0.00	0.00	0.00	4,142.75
Maximum IMI JU contribution	3,107.06	0.00	0.00	0.00	3,107.06
Requested IMI JU contribution					3,107.06

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?
If yes, please mention the amount (in €)

2b) Other receipts
Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. II.16 of the grant agreement?
If yes, please mention the amount (in €)

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. II.18 of the grant agreement?
If yes, please mention the amount (in €)

4- Certificate on the methodology

Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2. of the grant agreement, except for the final reporting period, Art. II.4.5 of the grant agreement.)

Name of the auditor

Cost of the certificate (in €)

6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. II.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANAGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. II.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	I.A. David Göbel
	Date & signature
	14-SEP-2018

Medizinische Hochschule Hannover
Zentrum Innere Medizin
Klinik für Pneumologie
Prof. Dr. med. T. V. ...
Carl-Neuberg-Straße 1 • 30625 Hannover

Medizinische Hochschule Hannover
Dnrmitteilabteilung
Carl-Neuberg-Straße 1 • 30625 Hannover

17.09.2018

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr Project Acronym	115721 iABC Programme	Funding scheme	IMI Research Project
Period from To	01/08/2016 31/07/2017	Is this an adjustment to a previous statement?	Adjustment to period 2
Legal Name Organisation short Name	MEDIZINISCHE HOCHSCHULE HANNOVER MHH	Participant Identity Code (PIC) Participant number in the project	999878426 14
Funding % for RTD activities (A)	75 %	Indirect Costs Method based on actual indirect costs? Method based on flat rate of 20 %?	No Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	3,452.29	0.00	0.00	0.00	3,452.29
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other-direct costs	0.00	0.00	0.00	0.00	0.00
Sub-total direct costs	3,452.29	0.00	0.00	0.00	3,452.29
Indirect costs	690.46	0.00	0.00	0.00	690.46
Total	4,142.76	0.00	0.00	0.00	4,142.76
Maximum IMI JU contribution	3,107.06	0.00	0.00	0.00	3,107.06
Requested IMI JU contribution					3,107.06

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?
If yes, please mention the amount (in €)

2b) Other receipts
Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. II.16 of the grant agreement?
If yes, please mention the amount (in €)

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. II.18 of the grant agreement?
If yes, please mention the amount (in €)

4- Certificate on the methodology

Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2. of the grant agreement, except for the final reporting period, Art. II.4.5 of the grant agreement.)

Name of the auditor

Cost of the certificate (in €)

6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. II.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANAGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. II.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	I.A. David Göbel
	Date & signature

Medizinische Hochschule Hannover
Zentrum Innere Medizin
Klinik für Pneumologie
Prof. Dr. med. T. V. ...
Carl-Neuberg-Straße 1 • 30525 Hannover

Medizinische Hochschule Hannover
DnrmitteLABteilung
Carl-Neuberg-Straße 1 • 30625 Hannover

17.09.2017

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	iABC Programme		

Period from	01/08/2017	Is this an adjustment to a previous statement?	No
To	31/07/2018		

Legal Name	University of Antwerp	Participant Identity Code (PIC)	999902870
Organisation short Name	UANTWERP	Participant number in the project	15

Funding % for RTD activities (A)	75 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	0.00	0.00	0.00	0.00	0.00
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	0.00	0.00	0.00	0.00	0.00
Sub-total direct costs	0.00	0.00	0.00	0.00	0.00
Indirect costs	0.00	0.00	0.00	0.00	0.00
Total	0.00	0.00	0.00	0.00	0.00
Maximum IMI JU contribution	0.00	0.00	0.00	0.00	0.00
Requested IMI JU contribution					0.00

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?

If yes, please mention the amount (in €)

No
0.00

2b) Other receipts

Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. II.16 of the grant agreement?

If yes, please mention the amount (in €)

No
0.00

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. II.18 of the grant agreement?

If yes, please mention the amount (in €)

No
0.00

4- Certificate on the methodology

Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?

Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

No
No

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2 of the grant agreement, except for the final reporting period; Art. II.4.5 of the grant agreement.)

No

Name of the auditor		Cost of the certificate (in €)	0.00
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6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. II.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANAGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. II.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	Prof. Herman Goossens
	Date & signature



IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	iABC Programme		

Period from	01/08/2017	Is this an adjustment to a previous statement?	No
To	31/07/2018		

Legal Name	THE UNIVERSITY OF EDINBURGH	Participant Identity Code (PIC)	999974941
Organisation short Name	UEDIN	Participant number in the project	16

Funding % for RTD activities (A)	75 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	0.00	0.00	0.00	0.00	0.00
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	0.00	0.00	0.00	0.00	0.00
Sub-total direct costs	0.00	0.00	0.00	0.00	0.00
Indirect costs	0.00	0.00	0.00	0.00	0.00
Total	0.00	0.00	0.00	0.00	0.00
Maximum IMI JU contribution	0.00	0.00	0.00	0.00	0.00
Requested IMI JU contribution					0.00

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?
If yes, please mention the amount (in €)

No
0.00

2b) Other receipts
Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. 11.16 of the grant agreement?
If yes, please mention the amount (in €)

No
0.00

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. 11.18 of the grant agreement?
If yes, please mention the amount (in €)

No
0.00

4- Certificate on the methodology

Do you declare average personnel costs according to Art. 11.13.2 of the grant agreement?
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. 11.13.2 of the grant agreement?

No
Yes

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. 11.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. 11.13.2 of the grant agreement, except for the final reporting period, Art. 11.4.5 of the grant agreement)

No

Name of the auditor		Cost of the certificate (in €)	0.00
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6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. 11.13 and 11.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. 11.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section 11.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANAGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. 11.18 of the grant agreement.

 The University of Edinburgh 16 Chambers Street Edinburgh EH1 1JT	Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
		Jennifer Mills
	Date & signature	Jennifer Mills 12/9/18

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by third party
 Only applicable if special clause 4 "Third parties linked to a participant" is used
 Not to be filled in by a third party linked to a managing entity (special clause 9) who must use the form for beneficiaries

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	IABC Programme		
Period from	01/08/2017	Is this an adjustment to a previous statement?	No
To	31/07/2018		
Third party legal Name	Lothian Health Board	Working for and linked to beneficiary nr	18
3rd party Organisation short Name	NHS Lothian		
Funding % for RTD activities (A)	75 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	17,209.41	0.00	0.00	0.00	17,209.41
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	0.00	0.00	0.00	0.00	0.00
Sub-total direct costs	17,209.41	0.00	0.00	0.00	17,209.41
Indirect costs	3,441.88	0.00	0.00	0.00	3,441.88
Total	20,651.29	0.00	0.00	0.00	20,651.29
Maximum IMI JU contribution	15,488.47	0.00	0.00	0.00	15,488.47
Requested IMI JU contribution					15,488.47

2- Declaration of receipts

Did you receive any financial transfers or contributions in kind, free of charge from third parties or did the project generate any income which could be considered a receipt according to Art. 11.16 of the grant agreement?
 If yes, please mention the amount (in €)

	No
	0.00

3- Certificate on the methodology

Do you declare average personnel costs according to Art. 11.13.2 of the grant agreement?
 Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. 11.13.2 of the grant agreement?

	No
	No

4- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. 11.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those third parties linked to a beneficiary that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. 11.13.2. of the grant agreement, except for the final reporting period: Art. 11.4.5 of the grant agreement.)


	No
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Name of the auditor		Cost of the certificate (in €)	0.00
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5- Third party's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. 11.13 and 11.14 and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. 11.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cf section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

Third party's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	Neil McLean
	Date & signature
	 12/09/18

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr Project Acronym	116721 IABC Programme	Funding scheme	IMI Research Project
Period from To	01/08/2017 31/07/2018	Is this an adjustment to a previous statement?	No
Legal Name Organisation short Name	Royal Brompton & Harefield NHS Foundation Trust RBHT	Participant Identity Code (PIC) Participant number in the project	999885507 17
Funding % for RTD activities (A)	75 %	Indirect Costs Method based on actual indirect costs? Method based on flat rate of 20 %?	No Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	43,512.74	0.00	0.00	0.00	43,512.74
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	2,684.57	0.00	0.00	0.00	2,684.57
Sub-total direct costs	46,197.31	0.00	0.00	0.00	46,197.31
Indirect costs	9,239.46	0.00	0.00	0.00	9,239.46
Total	55,436.77	0.00	0.00	0.00	55,436.77
Maximum IMI JU contribution	41,577.58	0.00	0.00	0.00	41,577.58
Requested IMI JU contribution					41,577.58

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?
If yes, please mention the amount (in €)

2b) Other receipts
Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. II.16 of the grant agreement?
If yes, please mention the amount (in €)

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. II.18 of the grant agreement?
If yes, please mention the amount (in €)

4- Certificate on the methodology

Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2 of the grant agreement, except for the final reporting period: Art. II.4.5 of the grant agreement.)

Name of the auditor

Cost of the certificate (in €)


6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. II.16 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANAGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. II.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
ROYAL BROMPTON & HAREFIELD NHS FOUNDATION TRUST	Anjulle Chana
	Date & signature
	23/05/18 

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr Project Acronym	115721 IABC Programme	Funding scheme	IMI Research Project
Period from To	01/08/2017 31/07/2018	Is this an adjustment to a previous statement?	No
Legal Name Organisation short Name	Papworth Hospital NHS Foundation Trust PAP	Participant Identity Code (PIC) Participant number in the project	951146305 19
Funding % for RTD activities (A)	75 %	Indirect Costs Method based on actual indirect costs? Method based on flat rate of 20 %?	No Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	7,659.47	0.00	0.00	0.00	7,659.47
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	8,600.00	0.00	0.00	237.97	8,837.97
Sub-total direct costs	16,259.47	0.00	0.00	237.97	16,497.44
Indirect costs	3,251.89	0.00	0.00	47.59	3,299.48
Total	19,511.36	0.00	0.00	285.56	19,796.92
Maximum IMI JU contribution	14,633.62	0.00	0.00	285.56	14,919.08
Requested IMI JU contribution					14,919.08

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?
If yes, please mention the amount (in €)

2b) Other receipts
Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. 11.16 of the grant agreement?
If yes, please mention the amount (in €)

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. 11.18 of the grant agreement?
If yes, please mention the amount (in €)

4- Certificate on the methodology

Do you declare average personnel costs according to Art. 11.13.2 of the grant agreement?
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. 11.13.2 of the grant agreement?

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. 11.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. 11.13.2. of the grant agreement, except for the final reporting period: Art. 11.4.5 of the grant agreement.)

Name of the auditor

Cost of the certificate (in €)

6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. 11.13 and 11.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. 11.15 of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section 11.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANAGING ENTITY

- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. 11.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	Sophia Jackson
	Date & signature
	S. Jackson 23.08.18

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	iABC Programme		

Period from	01/08/2017	Is this an adjustment to a previous statement?	No
To	31/07/2018		

Legal Name	ERASMUS UNIVERSITEIT MEDISCH CENTRUM ROTTERDAM	Participant Identity Code (PIC)	999988424
Organisation short Name	EMC	Participant number in the project	20

Funding % for RTD activities (A)	75 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	124,726.71	0.00	0.00	0.00	124,726.71
Subcontracting	29,472.94	0.00	0.00	0.00	29,472.94
Other direct costs	2,600.09	0.00	0.00	0.00	2,600.09
Sub-total direct costs	156,799.74	0.00	0.00	0.00	156,799.74
Indirect costs	25,465.36	0.00	0.00	0.00	25,465.36
Total	182,265.10	0.00	0.00	0.00	182,265.10
Maximum IMI JU contribution	136,698.83	0.00	0.00	0.00	136,698.83
Requested IMI JU contribution					136,698.83

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?	No
<i>If yes, please mention the amount (in €)</i>	0.00

2b) Other receipts	
<i>Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. II.16 of the grant agreement?</i>	No
<i>If yes, please mention the amount (in €)</i>	0.00

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

<i>Did the pre-financing you received generate any interest according to Art. II.18 of the grant agreement?</i>	No
<i>If yes, please mention the amount (in €)</i>	0.00

4- Certificate on the methodology

<i>Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?</i>	No
<i>Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?</i>	No


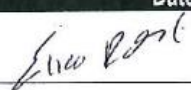
5- Certificate on the financial statements

<i>Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2 of the grant agreement, except for the final reporting period; Art. II.4.5 of the grant agreement.)</i>	No
Name of the auditor	
Cost of the certificate (in €)	0.00

6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
 - the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. II.16 of the grant agreement;
 - there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cfr section II.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives.
- ONLY FOR THE MANGING ENTITY
- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. II.18 of the grant agreement.

 <p>Postbus 2040 3000 CA Rotterdam</p>	Name of the Person(s) Authorised to sign this Financial Statement
	<p>Eliza Roest</p> <p>Date & signature</p> 

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr Project Acronym	115721 IABC Programme	Funding scheme	IMI Research Project
Period from To	01/08/2017 31/07/2018	Is this an adjustment to a previous statement?	No
Legal Name Organisation short Name	FUNDACIO HOSPITAL UNIVERSITARI VALL D'HEBRON - INSTITUT DE RECERCA VHIR	Participant Identity Code (PIC) Participant number in the project	999541642 21
Funding % for RTD activities (A)	75 %	Indirect Costs Method based on actual indirect costs? Method based on flat rate of 20 %?	No Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	26.833,83	0,00	0,00	0,00	26.833,83
Subcontracting	0,00	0,00	0,00	0,00	0,00
Other direct costs	475,80	0,00	0,00	0,00	475,80
Sub-total direct costs	27.309,63	0,00	0,00	0,00	27.309,63
Indirect costs	5.461,93	0,00	0,00	0,00	5.461,93
Total	32.771,56	0,00	0,00	0,00	32.771,56
Maximum IMI JU contribution	24.578,67	0,00	0,00	0,00	24.578,67
Requested IMI JU contribution					24.578,67

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?

If yes, please mention the amount (in €)

No
0,00

2b) Other receipts

Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. 11 16 of the grant agreement?

If yes, please mention the amount (in €)

No
0,00

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. 11 18 of the grant agreement?

If yes, please mention the amount (in €)

No
0,00

4- Certificate on the methodology

Do you declare average personnel costs according to Art. 11 13 2 of the grant agreement?

Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. 11.13 2 of the grant agreement?

No
No

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. 11 4 4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. 11 13 2 of the grant agreement, except for the final reporting period, Art. 11 4 5 of the grant agreement)


No

Name of the auditor		Cost of the certificate (in €)	0,00
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6- Beneficiary's declaration on its honour

We declare on our honour that

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. 11 13 and 11 14 of the grant agreement and Article 7 (special clauses) of the grant agreement.
 - the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. 11 16 of the grant agreement.
 - there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cf section 11 3 of Annex II) by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives
- ONLY FOR THE MANAGING ENTITY**
- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. 11 18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	Mo
	Date & signature
	22 AGO. 2018

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each beneficiary

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	iABC Programme		

Period from	01/01/2017	Is this an adjustment to a previous statement?	Adjustment to period 2
To	31/07/2017		

Legal Name	FUNDACIÓ HOSPITAL UNIVERSITARI VALL D'HEBRON - INSTITUT DE RECERCA	Participant Identity Code (PIC)	999541642
Organisation short Name	VHIR	Participant number in the project	21

Funding % for RTD activities (A)	75 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 20 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	2,149.16	0.00	0.00	0.00	2,149.16
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	0.00	0.00	0.00	0.00	0.00
Sub-total direct costs	2,149.16	0.00	0.00	0.00	2,149.16
Indirect costs	429.83	0.00	0.00	0.00	429.83
Total	2,578.99	0.00	0.00	0.00	2,578.99
Maximum IMI JU contribution	1,934.24	0.00	0.00	0.00	1,934.24
Requested IMI JU contribution					1,934.24

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPIA company?
If yes, please mention the amount (in €)

No
0.00

2b) Other receipts
Did you receive any financial transfers or contributions in kind, free of charge from third parties or from a participant under special clause 11, or did the project generate any income which could be considered a receipt according to Art. 11 16 of the grant agreement?
If yes, please mention the amount (in €)

No
0.00

3- Declaration of interest yielded by the pre-financing (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. 11 18 of the grant agreement?
If yes, please mention the amount (in €)

No
0.00

4- Certificate on the methodology

Do you declare average personnel costs according to Art. 11 13 2 of the grant agreement?
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. 11 13 2 of the grant agreement?

No
No

5- Certificate on the financial statements

Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. 11 4 4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. 11 13 2 of the grant agreement, except for the final reporting period, Art. 11 4 5 of the grant agreement)


No

Name of the auditor		Cost of the certificate (in €)	0.00
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6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. 11 13 and 11 14 of the grant agreement and Article 7 (special clauses) of the grant agreement;
 - the receipts declared above are the only financial contributions from EFPIA companies, financial transfers or contributions in kind, free of charge, from third parties and the only income generated by the project which could be considered as receipts according to Art. 11 16 of the grant agreement;
 - there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU and/or, if applicable (cf section II 3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or their authorised representatives
- ONLY FOR THE MANAGING ENTITY**
- the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. 11 18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	Mantse Gimenez
	D. tit & signature

22 AGO. 2018

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

ANNEX V - FORM C
FINANCIAL STATEMENT - to be filled in by each EFPIA company

Project nr	115721	Funding scheme	IMI Research Project
Project Acronym	iABC Programme		

Period from	01/08/2017	Is this an adjustment to a previous statement?	No
To	31/07/2018		

Legal Name	Polyphor AG	Participant Identity Code (PIC)	998273755
Organisation short Name	POL	Participant nbr	22

Indirect Costs	
Method based on actual indirect costs?	Yes
Method based on flat rate of 20 %?	No

1- Declaration of eligible in kind contribution (in €)

	Amount
Personnel costs	299,708.50
Subcontracting	122,759.98
Other direct costs	20,614.59
Indirect costs	0.00
Total	443,083.07

2- Declaration of Financial contribution

Did you provide any financial contribution to a beneficiary or to a participant under special clause 11?	No
If yes, please name the beneficiary(ies)/participants under special clause 11 to whom you provided a financial contribution	
Please mention the total amount (in €), if you provided a contribution	0.00

3- Total In Kind contribution (1 + 2)

Of which in kind contribution for research activities conducted outside a Member State or an associated country, in accordance with special clause 13 a) or b), if one of this special clauses applies	0.00
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4- Certificate on the methodology

Do you declare costs based on a certified methodology on in kind contribution according to Art. II.13.4 of the grant agreement?	No
Do you declare average personnel costs according to Art. II.13.2 of the grant agreement?	Yes
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. II.13.2 of the grant agreement?	No

5- Certificate on the financial statements


Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those EFPIA companies that declare costs on the basis of a certified methodology in accordance with Art. II.13.4 of the grant agreement, and for those EFPIA companies that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2. of the grant agreement, except for the final reporting period; Art. II.4.5 of the grant agreement.)	No
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Name of the auditor		Cost of the certificate (in €)	0.00
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6- EFPIA Company's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in Art. II.13 and II.14 and Article 7 (special clauses) of the grant agreement;
- there is full supporting documentation to justify the information hereby declared. It will be made available at the request of the IMI JU and in the event of an audit.

EFPIA company's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
POLYPHOR AG Hegenheimermattweg 125 CH-4123 Allschwil Tel: 061/567 16 00	Kalina Scott, Giacomo DiNepi, Helmut Kessmann, Daniel Obrecht, Debra Barker
	Date & signature  25.10.2018

Dr. Helmut Kessmann
Head Business Development

