

**Periodic project report
Inhaled Antibiotics in
Bronchiectasis and Cystic
Fibrosis
iABC**

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Period 08/2016 – 07/2017

Reporting Period 2

Description of work - 24 August 2015/DoW_0.5v with reference to
new DoW v2.0

Date of submission: 13.10.2017

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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: David L Hughes.....

Date:12...../ ..Oct...../ ..2017.....

Signature of the Coordinator:
 Digitally signed by Hughes David
DN: dc=com, dc=novartis, ou=people, ou=GD, serialNumber=1370161, cn=Hughes David
Date: 2017.10.12 01:55:47 +02'00'

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) referred to in the Y1 report on the project contained activities to deliver the objectives outlined below

1. To develop an inhaled formulation and dispersion device for BAL30072, a novel antibiotic with activity against a broad range of MDR Gram-negative pathogens (34, 35)
2. To determine the pharmacokinetics and safety of BAL30072 in CF and BE patients and to provide some initial efficacy data
3. To determine the therapeutic efficacy of Tobramycin inhaled powder (TIP) in BE patients
4. To explore novel endpoints (microbiome, LCI and CT imaging) for clinical trials in both CF and BE
5. To build repositories of clinical respiratory isolates and sputum biobanks for use in future research
6. 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.

However, at the beginning of Y2, activities 1 and 2 were placed on hold as, due to patient safety and programmatic issues, Basilea took the scientific decision to withdraw their IMP BAL30072 from the project. This necessitated the development of a new DoW throughout the year, with a new EFPIA partner in Polyphor Ltd. The activities added by the Polyphor work plan are

- Study the formulation of POL7080 in a preclinical setting to support the clinical development of inhaled therapy in patients with CF
- Establish the pharmacology, DMPK and non-clinical safety of POL7080
- 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 8 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
- WP2 supporting the pre-clinical development of BAL30072, is no longer active
- WP3 supporting the clinical development of BAL30072 for use in CF patients, is no longer active

- 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 second periodic report of the iABC consortium and most areas, in particular, WP5 continue to make significant progress. WP4 and WP6 ramped up activity as the iBEST-1 Phase II clinical trial commenced. BAL30072 Basilea Work-Packages (WP2, WP3 and WP4A) have now ceased, with the result that Basilea and Fraunhofer ITEM have now left the consortium. The withdrawal of BAL30072 also created a body of unforeseen activity this year in that it necessitated the search for a new EFPIA partner and the development of a new plan of work. The consortium Management Board actively sought proposals from interested parties and after a period of evaluation and negotiation, Polyphor Ltd was invited to join the project. Polyphor have brought their IMP POL7080 to the table and WP7 and WP8 have been developed to drive pre-clinical testing and a series of Phase I clinical trials. At the time of writing, the new DoW has been submitted to IMI. The consortium continues to work well as a team and we are confident as we begin the new body of work.

Significant achievements since last report

Key achievements this period include:-

- The EMBARC European Bronchiectasis Registry (WP5), coordinated by the University of Dundee continues to grow with more than 10,600 patients now enrolled across 24 countries.
- Clinical Trial Applications (CTA) were submitted and approved by Health Authorities of the 8 countries of iBEST-1 study. Drug packaging and supply was established in parallel to setting up electronic database and Novartis Interactive Response Technology (IRT) for complex trial design and patient randomization steam.
- The first patient on iBEST-1 Phase II clinical trial of inhaled TIP in BE patients was recruited on 2 February 2017. As of 12 September 2017, 43 sites have been initiated and 37 patients enrolled.
- Polyphor have joined the consortium following application selection process and a new Description of Work has been developed including the new development of Murepavadin (POL7080) for use in patients with Cystic Fibrosis.
- The central laboratory facilities at QUB, Antwerp and Rotterdam are operational, supporting the TIP Phase II trial.
- Installation of Lung Clearance Index (LCI) equipment has been installed at sites; 95% of staff are fully trained and certified and the first patients are being tested as part of the iBEST1 trial.

2 Summary of progress against objectives

2.1 Summary table

Work - Package Number	Milestone/ Deliverable (number and short title)	Date Due (Annex I- description of work)	Completed (Yes/Not yet/Partially)	Dissemination level ¹	Related document attached (Yes/No/Not applicable)
2	D2.3 Report on feasibility of BAL30072 as DPI	M15	Cancelled due to IMP withdrawal	N/A	Not applicable
2	D2.4 BAL30072 DPI (formulation + device)	M24	Cancelled due to IMP withdrawal	N/A	Not applicable
2	D2.5 BAL30072 in vitro microbiological testing results	M15	Partially, further work cancelled due to IMP withdrawal	N/A	Yes
2	D2.6 Biofilm testing of BAL30072 activity against CF pathogens completed	M15	Cancelled due to IMP withdrawal	N/A	Not applicable
2	D2.7 Biofilm model development and assessment of results.	M15	Partially. Results will be published in a scientific journal	PU	No
2	D2.10 BAL30072 in-vivo microbiological testing results.	M15	Cancelled due to IMP withdrawal	N/A	Not applicable
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 the LCI sub study (19 new sites and 8 sites with existing devices)	N/A	Yes
2	M2.3 Decision on whether to proceed to development of DPI device	M15	Cancelled due to IMP withdrawal	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	M2.4 Development of BAL30072 DPI formulation with a suitable device	M24	Cancelled due to IMP withdrawal	N/A	Not applicable
2	M2.5 <i>In vitro</i> microbiological testing of BAL 30072 against CF pathogens completed	M18	Cancelled due to IMP withdrawal	N/A	Not applicable
2	M2.6 Biofilm testing of BAL30072 activity against CF pathogens completed	M15	Cancelled due to IMP withdrawal	N/A	Not applicable
2	M2.7 In-vivo microbiological testing of BAL30072 against CF pathogens completed	M18	Cancelled due to IMP withdrawal	N/A	Not applicable
2	M2.8 Pre-clinical inhalation toxicology and toxicokinetics of BAL30072 completed. Decision on whether to proceed to Phase I clinical studies	M21	Cancelled due to IMP withdrawal	N/A	Not applicable
2	M2.9 Development of BAL30072 complete with a decision on whether to proceed to clinical trials	M21	Cancelled due to IMP withdrawal	N/A	Not applicable
4	M4.3 Site selection and pre-identification complete	M6	Completed	CO	Yes
4	M4.4 First patient first visit in Phase II trial of TIP	M9	Completed	PU	Yes
4	M4.5 Completion of enrolment in Phase II trial of TIP	M18	Not yet	N/A	Not applicable
4	M4.6 Last patient last visit in the Phase II trial of TIP	M24	Not yet	N/A	Not applicable

5	M5.2 Publication of research roadmap	M14	Completed	PU	D5.6 completed
5	M5.3 Enrolment of first 1000 patients	M14	Completed	PU	Yes
5	M5.4 Active participation of 20 European countries	M14	Completed	PU	Yes
5	M5.5 Enrolment of 4000 patients from at least 20 countries	M26	Completed	PU	Yes
5	M5.6 Enrolment of 6000 patients from at least 20 countries	M38	Completed	PU	Yes
6	M6.3 Purchase of Ecomedics Exhalyser D devices for MBW testing and training and qualification in LCI measurement in 25 centres in preparation for WP4B BE study	M7	Completed: 25 devices purchased. In total 19/25 devices installed at 19 sites. 1 returned as site cannot take part in LCI sub study Remaining devices (n=6) to act as a back up to sites active in LCI sub study.		Not applicable
6	M6.7 Website for standardization of chest CTs in Phase II and Phase III studies	M6+M35	Partially Protocols and SOPs for CT scanning are finalised. Website development in progress	N/A	Not applicable
6	M6.8 BE scoring baseline CTs: Image analysis baseline Phase II (Bauman and Hartmann scoring, PRAGMA-BE)	M8-18, M33	Not yet. Currently the transfer of CTs to Erasmus MC is in progress. To date 3 scans received.	N/A	Not applicable

The following activity has also taken place where no deliverables/milestones were foreseen for this period.

WP2

For the WGS of the CF-pathogens, over half of the strains have been sequenced, reference sequences have been partially constructed and some preliminary analyses have been performed. This work will be continued within WP7

WP6

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 has received 95 samples from 27 patients recruited to the study. Eighty-six *P. aeruginosa* isolates have been cultured with 3 *P. aeruginosa* isolates grown from cough swabs.

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 is currently being 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 which will enable us to determine if there is a correlation between *P. aeruginosa* load and relative abundance.

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

Work Package 2

Much of the work in WP2 was discontinued or cancelled due to the withdrawal of BAL30072 as the investigative compound. This includes all the pre-clinical toxicological testing of BAL30072, and the efficacy testing in animal models and biofilm models. Further work in WP2 which was foreseen to be performed in the second year included the development of an open biofilm model for assessment of antimicrobial activity, the development of a β ENaC-Tg mouse model of chronic pulmonary infection with *P. aeruginosa*, and the analysis of CF-pathogens by whole genome sequencing (WGS).

The development of the β ENaC-Tg mouse model and the biofilm model have largely been put on hold in the second year, as a new partner was sought with a new candidate compound. This work will be continued in WP7 with Polyphor and a new work plan.

For the WGS of the CF-pathogens, over half of the strains have been sequenced, reference sequences have been partially constructed and some preliminary analyses have been performed. This work will also be continued within WP7.

Work Package 4B

The delay in the start-up activities contracted with the ICON Contract Research Organization (CRO), are translated in the revised milestones as proposed in the amendment (FPFV initially planned for M15, achieved in M19). More detailed information is found in the aforementioned request for amendment #1 to the DoW.

In line with amendment #1, Phase II bronchiectasis study (iBEST-1 study) is projected to complete patient enrolment (M4.5) in M27 instead of M18 and overall complete (M4.6) in M33 instead of M24.

Work package 6

(D6.7) The roll out of the LCI sub trial continued through Period 2. It is planned that 27 sites will take part as part of the iBEST1 Phase II trial. To date a training programme has been developed and delivered to 20 sites. Certification is fully complete in 13 sites. Training is still outstanding at 2 sites and certification is ongoing at 14 sites. Certification has been delayed in some sites due to challenges in securing volunteers to complete the LCI measurement. The certification criteria were amended on 12th June to facilitate completion.

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)The protocols and SOPs for CT scanning are completed and agreed and website developers are finalising functional and layout design. It is estimated that on-line testing will complete and the system will be live by the end of 2017.

2.2 Deviations from Description of Work

The major deviations from the Description of Work are described in the Request for Amendment #1 submitted to IMI on 19th September 2017. These have been as a result of the withdrawal of BAL30072 from the project. This has necessitated the termination of WP2, WP3 and WP4A. The introduction of Polyphor to the consortium with their programme of development work for POL7080 has driven has been captured in WP7 and WP8. The scientific objectives, previously in WP2 will now be carried out within WP7 with some unavoidable repetition of the work already carried out for BAL30072.

The phase II bronchiectasis study in WP4B (iBEST-1) design has been revised following feedback from the regulatory authorities in Europe (EMA Scientific Advice received on 25 Jun 2015) and the USA (FDA type-C meeting on 23 Jun 2015). The following considerations have resulted in a revision of the study design, with an increased number of patients, an increase in visits and an increase in treatment duration versus original DoW. Amendment of the DoW was submitted for approved with revised timelines. Primarily due to the redesign to include more patients and complex public tender process and CRO contractual negotiations, the Phase II study (Study 4b) is projected to complete in M33 instead of M24 in the original plan with even a risk of completing. This has a considerable knock on effect on the Phase III plan, which taking into account all CRO study close out activity, is expected to complete in M71.

WP6 has been re-planned to support the timelines of the clinical trials contained in WP4 and WP8.

3 Summary of Major Achievements and key dissemination activities

3.1 Major achievements

As previously stated, this period has been dominated by the major changes in the consortium and the development of the new work plan in line with this. There are, however, some areas which have made considerable progress since the P1 report.

- The BE registry has at the time of writing more than 10,600 patients registered which is far beyond expectations at this stage of the project. Although patient registration is still ongoing and expected to reach 15,000 in the lifetime of iABC, the focus is now also turning towards sustainability and discussions are ongoing with interested parties.
- iBEST1 clinical trial has begun with 37 patients randomised at the time of writing and a plan of action in place to increase recruitment rates with a view to reaching 180 patients by M33.
- The LCI sub study has begun with a supporting training programme, and e-learning tool and a central LCI reading service in place at QUB
- Standard protocols for DNA extraction, PCR, NGS and CT scanning have been developed and are in use with the iBEST1 study.

3.2 Key dissemination activities

Nature of Communication	Title	Responsible Participant (and presenter when relevant)	Date/location when relevant.	Target audience
Oral presentation website poster	On-line standardisation of CT scanning in cystic fibrosis trials	Prof. H. Tiddens	02-15-2017	Research young investigators Cystic Fibrosis
Presentation of preliminary results of systematic review	How to diagnose and quantify bronchiectasis	Prof. H. Tiddens	05-06-2017	Standardization group
Plenary Presentation	Imaging inflammation- can we phenotype by CT	Prof. H. Tiddens	05-06-2017	2nd World Bronchiectasis Conference
Poster presentation	Dose finding study to find the efficacy, safety and tolerability of tobramycin inhalation powder in patients with non-cystic fibrosis bronchiectasis and pulmonary <i>P.aeruginosa</i> infection (iBEST-1)	Michael Loebinger and Gerhild Angyalosi	7 th July 2017/ World BE conference, Milan	Scientific community, patients organisations

Paper publication	Patient participation in ERS guidelines and research projects: the EMBARC experience	James Chalmers	Sept 2017 Breathe	Scientific community, patients organisations
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Papers are ongoing in the following areas and publication is planned in P3

- UMCU and SERMAS are currently working on two publications on susceptibility results and preliminary evaluation of the open biofilm model developed in work package 2.
- Publication of the 1st manuscript related to the EMBARC/iABC registry

3.3 Use and dissemination of foreground

Not applicable during this period

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 1 with strong collaboration among the consortium. The withdrawal of the Basilea IMP BAL30072 as reported at the end of P1 presented the largest challenge in that an immediate hold was placed on the work being carried out by some partners until a replacement body of work could be found.

The Management Board undertook the task of finding suitable proposals which would enable the project to continue, while keeping the wider community informed of progress. These received proposals were evaluated against a number of criteria and the group decided that Polyphor provided the best fit for the consortium. All partners were consulted on the new Description of Work which was developed and agreed at two workshop meetings in London in April and Basel in May. At the time of writing a request for amendment to the Grant Agreement has been submitted and a new Project Agreement circulated among the partnership for signature. We are happy to welcome Polyphor Ltd and Vall D’Hebron Institut de Recerca as new consortium members in P2 and wish to thank Basilea, Fundacio Clinic per a la Recerca Biomedica and Fraunhofer ITEM for their contributions as they leave the group.

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 meeting was this year held at the World Bronchiectasis conference in Milan in July with all partners represented. We reviewed P2 and the progress which had been made so far and this was also the opportunity to introduce the new partners and reset the project plan.

The iABC project is represented at the ND4BB meetings and the interaction with other members of this group in conjunction with EFPIA proved invaluable in the consortium search for a potential new partner. 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 P1 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

P3 of the project begins with the approval of a new Description of Work V2.0. The DoW now includes two new work packages WP7 and WP8 and work packages WP2, WP3, WP4a have been removed as per the table below. Approval has also been given to extend the project with no extra cost until December 2021.

Work-package No.	Work-package title	Type of activity	Lead part. No.	Person-months	Start month	End month
WP1	Project management and Communication	MGT	1	220	1	77
WP2	<i>Pre-clinical development of BAL30072 as inhalation therapy: formulation development and device selection. Work Package 2 is no longer active following the termination of BAL30072-related</i>	RTD	4	110	1	23
WP3	Work Package 3 is no longer active following the termination of BAL30072-related activities.					
WP4	Antibacterials in patients with Bronchiectasis (Clinical studies). WP4A has been removed due to the termination of BAL30072 related activities	RTD	12	516.33	1	77
WP5	Development of an EU bronchiectasis registry	RTD	10	210	1	77
WP6	Novel outcome measures for clinical trials	RTD	2	580	1	77
WP7	Pre-clinical development of POL7080 as an inhalation therapy: formulation development and device selection	RTD	3	179	24	60
WP8	Clinical development of POL7080 for use in patients with Cystic Fibrosis (clinical studies)	RTD	3	79.57	45	77

The deliverables and milestones planned for this period are as follows:

Del. No.	Deliverable name	WP No.	Nature	Delivery date
D6.7	Selected sites involved in LCI measurement for BE Phase II study set up and trained	6	O	M26
D4.2	Phase II trial of TIP in BE patients (abbreviated report of key 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 exploratory molecular and conventional microbiological endpoints.	6	R	M33
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	M33
D6.15	Analysis of sputum inflammatory biomarker data collected in Phase 2 TIP dose finding study and comparison with conventional and other exploratory endpoints	6	R	M33
Milestone No.	Milestone name	WPs involved	Expected delivery date	Means of verification
M4.5	Completion of enrolment in Phase II trial of TIP	4	M27	CRO report received
M4.6	Last Patient last visit in the Phase II TIP study	4	M35	CRO report received
M5.5	Enrolment of 4000 patients from at least 20 EU Countries.	5	M26	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 measure in Phase II TIP BE study (WP 4B).	6	M35	Abstracts at scientific conferences and journal 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
M6.9	Exploratory sputum inflammatory biomarker endpoints determined	6	M35	Abstracts at scientific conferences and journal article
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.	7	M36	D7.1
M7.3	M7.3.1 In vitro microbiological testing of POL7080 activity against Pa from CF and BE patients completed.	7	M36	D7.3
M7.4	M7.4.2 Calgary biofilm susceptibility raw data available to establish adequate dosage in animal model.	7	M34	

At this stage of the project, no discussions have taken place regarding the sustainability beyond the end of the project.

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
WP1 Reduced project delivery time in WP7 & WP8 due to delay in development of the new DoW.	H	H	Close collaboration with all consortium partners and careful management of the project plan.	All consortium partners	Weekly meetings with partners to monitor progress and rapid escalation and resolution of issues	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
WP4B iBEST-1 Study timelines	L	M	Close collaboration with CRO for sites selection and initiation	NVS/QUB/PAP/RBHT/UNIVDUN/UMIL/FCRB/UEDIN	Weekly monitoring, TSC actively engaged in new site identification.	ongoing
WP4B iBEST-1 budget	L	L		QUB/NVS	Close tracking of the CRO spending	ongoing
WP4B Phase-III study budget	H	H	Consider re-design the phase III programme based on Phase II results	QUB/NVS	On completion of the phase II study, the consortium shall take action to re-design the phase III programme and examine the options for funding at that time.	M34

WP4B Recruitment slower than expected in Phase II	H	H	Recruiting from up to 49 leading European centres with a target of 4 per site. This is based on previous studies of similar size and design (has been shown to be achievable. Recruitment from ECFS-CTN and EMBARC centres with proven record.	NVS/QUB/P AP/RBHT/U NIVDUN/U MIL/FCRB/ UEDIN and ICON	Close monitoring of recruitment rates with CRO and selection of backup sites. Actions being taken by TSC to contact sites individually and assist.	M28
WP4B Imbalance in recruitment between countries	H	L	Steps being taken to moderate recruitment in the UK and enhance recruitment elsewhere	UoD	As described	M28
WP5 Over-recruitment	M	M	Steps being taken to ensure the sustainability of the project and to potentially permit over recruitment	UoD	As described	M25
WP5 Loss of ERS endorsement	L	H	ERS endorsement expired in April 2017 and requires to be renewed. The likelihood of failing renewal is low but impact would be high	UoD	ERS have verbally agreed to continue endorsement , and formal letter is anticipated but will be monitored	M25
M6.7 Website for standardization of chest CTs not ready before start of Phase II study	L	L	We can communicate CT protocols per email when required.	Prof. H. Tiddens	Progress is closely monitored. Roll out of website planned in Q4 2017	M28

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**

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

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

Project nr	116721	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	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	0.00	0.00	0.00	0.00	0.00
Subcontracting	4,717.52	0.00	0.00	0.00	4,717.52
Other direct costs	-196,213.33	-272.13	0.00	0.00	-196,485.46
Sub-total direct costs	-191,495.81	-272.13	0.00	0.00	-191,767.94
Indirect costs	-39,242.67	-54.43	0.00	0.00	-39,297.10
Total	-230,738.48	-326.56	0.00	0.00	-231,065.04
Maximum IMI JU contribution	-173,053.86	-326.56	0.00	0.00	-173,380.42
Requested IMI JU contribution					-173,380.42

2- Declaration of receipts

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


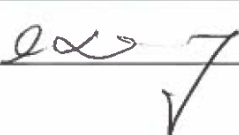
Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
 QUEEN'S UNIVERSITY BELFAST RESEARCH SUPPORT OFFICE	Aveen Lavery
	Date & signature  13/10/17

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Partner 4 Universitair Medisch Centrum Utrecht (UMCU)

Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
	Personnel direct costs	€ 88.182	<i>This costs are only the hours of all project staff;</i> <ul style="list-style-type: none"> • 1 PI, 1 PostDoc., 1 Researcher, 1 Research Technician
	Subcontracting <i>[if foreseen in Description of Work]</i>	€ 0	
	Other direct costs	€ 1.095	<i>This costs include travel and benchfee 2016 and 2017;</i> <ul style="list-style-type: none"> • Hotel, flight, Basel 18-05-2017 (M. Ekkelenkamp) • Hotel, flight, Londen 03-04-17 (M. Ekkelenkamp) • Hotel, flight, Milan 05-07-17 (M. Ekkelenkamp)
	<i>Consumables [if applicable]</i>	€ 32.002	€90k WGS
	<i>Equipment depreciation [if applicable]</i>	€ 0	<i>depreciation of important equipment (provide detail)</i>
	<i>Hardware/Software/licence costs</i>	€ 0	
	Indirect costs	€ 24.255,80	<i>e.g. 20% flat rate, actual indirect costs (€ 121.279*0,20)</i>
TOTAL COSTS		€ 145.534,80	
Budget for the period		€ 112.213,20	
Deviation		€ 33.321,60	

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Partner 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		<i>e.g. salaries of 2 postdoctoral students</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		<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

Partner no. 6 Fraunhofer-Gesellschaft Period 1 Adjustment			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
WP2	Personnel direct costs	564,71	<i>Post-calculation of personnel hourly rates 2016.</i>
	Subcontracting <i>[if foreseen in Description of Work]</i>	0,00	
	Other direct costs	0,00	
	Indirect costs	332,97	<i>Actual indirect costs linked to personnel costs.</i>
TOTAL COSTS		1.476,28	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Partner no.6		Fraunhofer-Gesellschaft Period 2	
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
WP2	Personnel direct costs	736,31	<i>Salaries of 1 scientist for 0.08 PM.</i>
	Subcontracting <i>[if foreseen in Description of Work]</i>	0,00	
	Other direct costs	0,00	
	Indirect costs	739,97	<i>Actual indirect costs based on personnel costs.</i>
TOTAL COSTS		1.476,28	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Partner 7 – Rijksuniversiteit Groningen (RUG)

Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
2	Personnel direct costs	25691.14	Salary postdoc 6 pm
2		10436,40	
2		1330.88	Salary technician 2.8 pm
2		14039,48	Salary professor 0.1 pm Salary phd 6 pm
	Subcontracting [if foreseen in Description of Work]		
	Other direct costs		
	Consumables [if applicable]		
	Equipment depreciation [if applicable]	1811,32	Loop-5 months depreciation a 362,3 = 1811: ((Amount 19200, date invoice 29-3-2016, total depreciation months 53, this period 5) (Months march until july)
	Equipment depreciation [if applicable]	541,98	Dehumidifier-5 months depreciation a 108,40 = 542: ((Amount 5745, date invoice 29-3-2016, total depreciation months 53, this period 5)
	Equipment depreciation [if applicable]	4304,09	Demo Discovery TGA-5 months depreciation a 860,8 = 4304: ((Amount 47345, date invoice 18-1-2016, total depreciation months 55, this period 5)
	Equipment depreciation [if applicable]	1862,84	Inhaler5 months depreciation a 372,6 = 1863: ((Amount 21609, date invoice30-10-2015, total depreciation months 58, this period 5)
	Other [if applicable]	0	Lab chemicals
	Other	29,36	Lab supplies
	Other	0	Travel costs Basel 6-6-2016/7-6-2016 meeting IABC
	Indirect costs	12009,50	
TOTAL COSTS		72056,99	
Budget for the period		127015	
Deviation		54958,01	Project "paused" from 2016-8 till 2017-02

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Partner 8 – Servicio Madrileño de Salud (SERMAS) ADJUSTMENT PERIOD 1

Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources
WP2	Personnel direct costs	1095.61 €	<i>Adjustment of the P1 report due to the fact that, in P1 we had calculated the cost per hour only considering the gross salary but in this adjustment we have also included the social security charges. 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	219.12 €	e.g. 20% flat rate, actual indirect costs
TOTAL COSTS		1314.73 €	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Partner 8 – Servicio Madrileño de Salud (SERMAS) PERIOD 2

Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources
WP2	Personnel direct costs	34715.53 €	<i>PM (Hired personnel cost: María Díez (22,713.39 € = 5PM) + Own-Staff Personnel cost; R.Cantón, MI. Morosini, M.Tato (12002.14 € = 2.3PM)</i>
	Subcontracting <i>[if foreseen in Description of Work]</i>		
	Other direct costs	3423,18 €	
WP2	<i>Consumables [if applicable]</i>	2843.41 €	<i>Microwell Plates F96 (204.96 €), Bioflux-48 Microwell Plates (2094.40 €), culture media (215.10 €), immuno plates (328.95€).</i>
WP2	<i>Travel</i>	579.77 €	<i>Attendance of Rafael Cantón to the ANNUAL GENERAL ASSEMBLY MEETING i-ABC. (Milan, Italy. 06/07/17). FLIGHT MADRID-MILAN (320€). Hotel (182 €), Subsistence cost, taxi ticket (77.77€).</i>
	<i>Equipment depreciation [if applicable]</i>		
	<i>Hardware/Software/licence costs</i>		
	Indirect costs	7627,74 €	e.g. 20% flat rate, actual indirect costs
TOTAL COSTS		45766.45 €	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Partner 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	64 956.54	Salaries of 3 junior lab personnel 5.1 PM 1 senior lab personnel 1.7 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]	3 074.16	Lab consumables
WP6	Equipment depreciation [if applicable]	4 078.01	Depreciation 5 years of -80°C freezer This has been calculated according to the local deprecation rules
WP6	Other [if applicable]	10 341.00	ICT consumables – support package
	Indirect costs	16489.94	e.g. 20% flat rate, actual indirect costs
TOTAL COSTS		98 939.65	
Budget for the period		292134.60	Overall WP6 budget divided by 5 (project runs for 5 years)
Deviation		-193 194.95	Total cost – budget for period

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Participant no.10 University of Dundee (UNIVDUN) RP1 ADJUSTMENT

Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources
5	Personnel direct costs	€67,598.35	Keith Milburn, Database Coordinator, 10.66PM, €51,350.52, moved from 'Other', add €10,755.41 as not fully charged. James Chalmers, Principle Investigator, charge miscalculated, €5,492.42.
5	Subcontracting	€17,561.02	Recruitment of patients at study sites moved from 'Other'.
	Other direct costs		
5	Consumables	- €544.51	Move document translation costs to 'Other', - €660.51. Add back VAT removed twice from project, €67.27. Move consumables from Other, €48.73.
5	Travel	€15,099.91	Travel costs moved from 'Other'.
	Other	- €83,860.82	Remove Keith Milburn salary, - €51,350.52. Remove travel, - €15,099.91. Remove patient costs, - €17,561.02. Add translation costs, €660.51. Remove VAT, - €67.27. Remove consumables, - €48.73. Remove transaction wrong project, - €393.88.
	Indirect costs	-€341.42	Flat rate at 20%, except subcontracting.
TOTAL COSTS		€15,512.53	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Participant no.10 University of Dundee (UNIVDUN) Period 2

Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources
5	Personnel direct costs	€183,149.13	Megan Crichton, Research Assistant, 12PM. Gayle Scott, Project Manager, 8.07PM. Samantha Thomson, Clerical Assistant, 7.26PM. Keith Milburn, Database Coordinator, 10.02PM. James Chalmers, Principle Investigator, 3.2PM RTD, 0.04PM Management.
5	Subcontracting	€147,646.84	Payments for enrolment of patients to study sites.
	Other direct costs		
5	Consumables	€28,781.08	Ultra-low temperature freezer and racking for storage of study samples. Computing equipment for study staff including monitor, 2x docking stations, 2x EliteBook 840. General admin consumables.
5	Travel	€12,623.68	Reimbursement of patient travel costs. Meeting with the US bronchiectasis registry and European Bronchiectasis Registry, Hanover, 5-13 July 2016, Anne O'Donnell. Spirometry Course Edinburgh Royal Infirmary, Gayle Scott, 1-2 September 2016; Pauline Billingham, 5 May 2016; Gillian Brady, 28 April 2016; Samantha Thomson, 29 March 2017. American Thoracic Society Conference, 13-18 May 2016, San Francisco, USA, Megan Crichton. European Respiratory Society International Congress, 3-7 September 2016, London, Megan Crichton, James Chalmers. 2nd World Bronchiectasis Conference, 6-8 July 2017, Milan, Megan Crichton, Gayle Scott. 1st World Bronchiectasis Conference, 7-9 July 2016, Hanover, Germany, James Chalmers, Megan Crichton, Gayle Scott, Robert Wilson. American Thoracic Society Conference, 19-24 May 2017, Washington, USA, Megan Crichton.
5	Other	€477.08	Document translation costs.
	Indirect costs	€45,006.19	20% flat rate, except subcontracting.
TOTAL COSTS		€417,684.00	
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
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		
	<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	0	20% flat rate
TOTAL COSTS		0	
Budget for the period			
Deviation			

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		<i>Salary costs for 1 Scientist/Lead Investigator</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	0	20% flat rate
TOTAL COSTS		0	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Partner 12 Università degli Studi di Milano (UMIL)

Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
WP1 AND WP4	Personnel direct costs	22,518.64	2.5 M/M effort of Prof. Francesco Blasi: <ul style="list-style-type: none"> • 1.84 M/M for activities related to WP4 • 0.66 M/M for activities related to WP1
	Subcontracting [if foreseen in Description of Work]	0	
	Other direct costs	0	
	Consumables [if applicable]	0	
	Equipment depreciation [if applicable]	0	depreciation of important equipment (provide detail)
	Hardware/Software/licence costs	0	
	Indirect costs	4,503.73	20% flat rate
TOTAL COSTS		27,022.37	
Budget for the period			
Deviation			No significant deviation has to be signalled. Also for the second reporting period, only Prof. Blasi participated in the project development. The recruitment procedure for a post doc position has already started and the contract will start in October 2017.

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Partner 1201 IRCCS CA' GRANDA OSPEDALE MAGGIORE POLICLINICO

Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
...	Personnel direct costs	€ 0	
	Subcontracting [if foreseen in Description of Work]	€ 0	
	Other direct costs		
WP4	Screening 1 st patient	€ 28,03	Informed Consent
		€ 60,07	Medical History, BE-Related Medical History, Smoking History, Pulmonary Exacerbations History, Demographics
		€ 28,03	Inclusion/Exclusion
		€ 88,11	Physical Exam
		€ 28,03	Vital Signs, Height and Weight
		€ 28,03	Central Labs (Collect, Process, Shipment)
		€ 20,02	Sputum Culture for P. Aeruginosa
		€ 44,05	ECG
		€ 56,07	Spirometry including interpretation and report
		€ 16,02	Review Concomitant Medications
		€ 20,02	SAE/Adverse Events
		€ 24,03	Randomization/Contact IRT
		€ 44,05	Study Coordinator Fee
WP4	Screening 2 nd patient	€ 28,03	Informed Consent
		€ 60,07	Medical History, BE-Related Medical History, Smoking History, Pulmonary Exacerbations History, Demographics
		€ 28,03	Inclusion/Exclusion
		€ 88,11	Physical Exam
		€ 28,03	Vital Signs, Height and Weight
		€ 28,03	Central Labs (Collect, Process, Shipment)
		€ 20,02	Sputum Culture for P. Aeruginosa
		€ 44,05	ECG
		€ 56,07	Spirometry including interpretation and report
		€ 16,02	Review Concomitant Medications
		€ 20,02	SAE/Adverse Events
		€ 24,03	Randomization/Contact IRT
		€ 44,05	Study Coordinator Fee
	Indirect costs	€ 193,82	e.g. 20% flat rate, actual indirect costs
TOTAL COSTS		€ 1162,94	
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
4	Personnel direct costs		<i>Eg Salary costs for 1Scientist/Lead Investigator</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	0	20% flat rate
TOTAL COSTS		0	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Partner 14 - Medizinische Hochschule Hannover (MHH)

Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
WP4A	Personnel direct costs	4.590,62	<i>1 Technican 0,55 Months, 1 Technican 0,37 Months</i>
	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	918,12	<i>e.g. 20% flat rate, actual indirect costs</i>
TOTAL COSTS		5.508,74	
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		<i>Salary costs for 1 Scientist/Lead Investigator</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	0	20% flat rate
TOTAL COSTS		0	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Partner 16 University of Edinburgh (UEDIN) – Period 2

Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
...	Personnel direct costs		
	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	0	20% flat rate
TOTAL COSTS		€0	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Partner 1601 NHS Lothian– Period 2

Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
...	Personnel direct costs	17,514.53	<i>Adam Hill, PI, 1.2PM</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>Other: Travel</i>		
	Indirect costs	3,502.91	<i>20% flat rate</i>
TOTAL COSTS		€21,017.44	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Partner 17 Royal Brompton & Harefield NHS Foundation Trust (RBHT) Period 2

Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
WP4	Personnel direct costs	28,874.68	Salary cost for Principal Investigator Dr Michael Loebinger.
	Subcontracting <i>[if foreseen in Description of Work]</i>		
	Other direct costs		
WP4	<i>Consumables [if applicable]</i>	1,594.64	<i>Consumables for carrying out Lung Clearance Index (LCI) tests for iBEST1 clinical trial</i>
	<i>Equipment depreciation [if applicable]</i>		<i>depreciation of important equipment (provide detail)</i>
	<i>Hardware/Software/licence costs</i>		
	Indirect costs	6,093.86	<i>e.g. 20% flat rate, actual indirect costs</i>
TOTAL COSTS		36,563.18	
Budget for the period		32,802.80	
Deviation		3,760.38	

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

PARTNER 18 FUNDACIO CLINIC PER A LA RECERCA BIOMEDICA (FCRB) ADJUSTMENT TO PERIOD 1

Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
WP4	Personnel direct costs	571.03	<i>Adjustment due to a mistake on the calculation of personnel costs corresponding to Eva Polverino (IP). Tasks developed in the framework of WP4 (1.94 PM).</i>
	Subcontracting [if foreseen in Description of Work]	0,00	
	Other direct costs	0,00	
	Indirect costs	114.21	<i>20% flat rate, actual indirect costs</i>
TOTAL COSTS		685.24	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

PARTNER NO. 18 FUNDACIO CLINIC PER A LA RECERCA BIOMEDICA (FCRB) PERIOD 2

Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
WP4	Personnel direct costs	3,050.09	<i>Personnel costs corresponding to Eva Polverino (IP). Tasks developed in the framework of WP4 (0.83 PM).</i>
	Subcontracting [if foreseen in Description of Work]	0,00	
	Other direct costs	0,00	
	Indirect costs	610.02	<i>20% flat rate, actual indirect costs</i>
TOTAL COSTS		3,660.11	
Budget for the period		4,240.00	
Deviation		-579.89	

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Participant no. 1801 Hospital Clínic i Provincial de Barcelona (HCPB)

Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
	Personnel direct costs		<i>Salary costs for 1Scientist/Lead Investigator</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	0	20% flat rate
TOTAL COSTS		0	
Budget for the period			
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Partner 19 Papworth Hospital NHS Foundation Trust (PAP)

Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
WP4	Personnel direct costs	3017.57 26070.16	<i>Dr Haworth's CI time commitment</i> <i>Research Nurse Support for WP4 iBEST1 clinical trial</i>
	Subcontracting [if foreseen in Description of Work]		
	Other direct costs		
WP4	<i>Travel</i>	434.50	<i>Dr Haworth travel to the General Assembly meeting held in Milan 7th July 2017</i>
	<i>Consumables [if applicable]</i>		
	<i>Equipment depreciation [if applicable]</i>		<i>depreciation of important equipment (provide detail)</i>
	<i>Hardware/Software/licence costs</i>		
	Indirect costs	5904.45	<i>e.g. 20% flat rate, actual indirect costs</i>
TOTAL COSTS		35426.68	
Budget for the period		<i>2nd Year</i>	
Deviation			

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING

Partner 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	71.388,60	<i>PHD student €55.429,28. Research Supervisor €4.698,01 Lung Analysis €11.261,31</i>
	Subcontracting <i>[if foreseen in Description of Work]</i>		
WP6	Other direct costs	927,39	<i>Travel costs PHD student J.J. Meerburg travelled to Basel on 06-06-2016 for General assembly iABC</i>
	<i>Consumables [if applicable]</i>		
	<i>Equipment depreciation [if applicable]</i>		<i>depreciation of important equipment (provide detail)</i>
	<i>Hardware/Software/licence costs</i>		
	Indirect costs	14.463,20	<i>e.g. 20% flat rate, actual indirect costs</i>
TOTAL COSTS		86.779,18	
Budget for the period			
Deviation			

- Reporting of costs incurred by EFPIA companies

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
[1-Basilea Pharmaceutica International AG] –			
Work relevant to Work-Package(s)	Item description	Amount in €	Explanations of the use of resources
...	Personnel direct costs	73'698.00	e.g work related to WP1 and WP2: Management and coordination activities, amndment of DoW, preparing periodic report for Y1 (WP1), finalisation of feasibility report (WP2),
	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		only if not included in FTE, according to certified methodology
	Sub-total in kind contribution	73'698.00	
	Direct financial contribution		
	Total in kind contribution	73'698.00	
	Of which Non-EU in kind contribution²		Please specify the type of costs
	Budget for the period	239'481	
	Deviation	-165'513	A full review of the available data package for BAL30072 has lead to the withdrawal of BAL30072 IMP by Basilea from Consortium activities. As a result of the withdrawal of BAL30072 from the Consortium it was required to amend the Description of Work to appropriately reflect the amended scope, timelines, and costs.

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 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)	1,834,857.53	9.22 fully loaded FTEs (=110.7 PMs) engaged in: <ul style="list-style-type: none"> • 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), study general governance (TSC), management of CRO and vendors, regulatory activities (DRA Hub), patient randomization and Supply testing, packaging and management • WP6: Co-leader and support to all activities linked to Bronchiectasis Phase-2 study
WPs: 4B	Subcontracting [if foreseen in Description of Work]	531,143.31	WP4B: Ongoing contracts with 4 vendors on iBEST-1 Phase-2 study
WPs: 4B	Consumables [if foreseen in Description of Work]	0.0	Note: WP4B: Consumables i.e. Tobramycin Inhaled Powder supply manufacturing costs, not included in this PY2 reporting. Actuals may be added as PY1 and/or PY2 adjustment
	Sub-total in kind contribution	2,366,000.84	
	Direct financial contribution	752,580.38	WP1 & WP6: QUB (Queen's University Belfast)
	Total in kind contribution	3,118,581.22	
	Of which Non-EU in kind contribution³	1,434,344.37	WP 4B: Novartis clinical and technical team members located in East Hanover (NJ, USA) and San Carlos (CA, USA)
	Budget for the period	3,982,043.00	1/5 of total commitment
	Deviation	-863,461.78	[Note: WP4B Consumables not yet included]

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

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	IABG Programme		
Period from	01/08/2016	Is this an adjustment to a previous statement?	No
To	31/07/2017		
Legal Name	Beeles Pharmaceuticals International AG	Participant Identity Code (PIC)	952807810
Organisation Short Name	Beeles	Participant nr	1

Included Costs	
IMU of fund-related indirect costs?	Yes
IMU of fund on the rate of 20%?	No

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

	Amount
Personnel costs	73,987.98
Subcontracting	0.00
Other direct costs	0.00
Indirect costs	0.00
Total	73,987.98

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)

73,987.98

Of which in-kind contribution for research activities conducted outside a Member State or an associated country, in accordance with special clause 11 a) or b), if one of this special clauses applies

0.00

4- Certificate on the methodology

Do you declare costs based on a certified methodology or in-kind contribution according to Art. 11.3.4 of the grant agreement?

Yes

Do you declare average personnel costs according to Art. 11.3.2 of the grant agreement?

No

Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. 11.3.2 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. 11.4.4 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. 11.3.4 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. 11.3.2 of the grant agreement, except for the first funding period: Art. 11.4.5 of the grant agreement.)

No

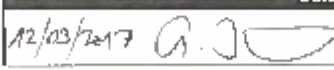
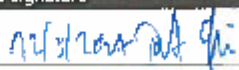
Name of the auditor		Cost of the certificate (in €)	0.00
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5- EFPIA Company's declaration on its honour

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. 11.13 and 11.14 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
	Andreas Kömle, Patrick Gotsch
	Date & signature
	12/03/2017  12/03/2017 

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?	No
To	31/07/2017		

Legal Name	Novartis Pharma AG	Participant Identity Code (PIC)	899754567
Organisation short Name	NOV	Participant nbr	3

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	1,834,857.53
Subcontracting	631,148.31
Other direct costs	0.00
Indirect costs	0.00
Total	2,366,000.84

2- Declaration of Financial contribution

Did you provide any financial contribution in a secondary 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

QUB (Queen's University Belfast)

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

752,580.38

3- Total in Kind contribution (1 + 2)

3,118,581.22

Or 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 the special clauses applies

1,434,344.37

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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B- 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
Novartis Pharma AG P.O. Box CH-4002 Basel	Vincent Malaterra, Global Program Team Director; Sebastian Schloechtriem, Head Finance Development Respiratory & E
	Date & signature
	25/05/2017 

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	01/08/2016	Is this an adjustment to a previous statement?	No
To	31/07/2017		

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	183,593.79	157,460.19	0.00	0.00	341,053.98
Subcontracting	1,794,934.70	0.00	0.00	0.00	1,794,934.70
Other direct costs	272,624.80	0.00	0.00	0.00	272,624.80
Sub-total direct costs	2,251,153.29	167,460.19	0.00	0.00	2,408,613.48
Indirect costs	91,243.72	31,492.04	0.00	0.00	122,735.76
Total	2,342,397.01	188,952.23	0.00	0.00	2,531,349.24
Maximum IMI JU contribution	1,756,797.76	188,952.23	0.00	0.00	1,945,749.99
Requested IMI JU contribution					1,945,749.99

2- Declaration of receipts

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

Yes
672,796.38

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.)

Yes

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. 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 MANGING 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
 QUEEN'S UNIVERSITY BELFAST RESEARCH SUPPORT OFFICE	Aveen Lavery
	Date & signature 13/10/17

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

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	0.00	0.00	0.00	0.00	0.00
Subcontracting	4,717.52	0.00	0.00	0.00	4,717.52
Other direct costs	-196,213.33	-272.13	0.00	0.00	-196,485.46
Sub-total direct costs	-191,495.81	-272.13	0.00	0.00	-191,767.94
Indirect costs	-39,242.67	-54.43	0.00	0.00	-39,297.10
Total	-230,738.48	-326.56	0.00	0.00	-231,065.04
Maximum IMI JU contribution	-173,053.86	-326.56	0.00	0.00	-173,380.42
Requested IMI JU contribution					-173,380.42

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 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
 QUEEN'S UNIVERSITY BELFAST RESEARCH SUPPORT OFFICE	Aveen Lavery
	Date & signature
	13/10/17

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

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

Project nr Project acronym	116721 IAGC Programme	Funding scheme	IMI Research Project
Period from To	01/08/2016 31/07/2017	Is this an adjustment to a previous statement?	No
Legal name Localisation (city name)	University Medical Center Utrecht UMCU	Participant Identity Code (PIC) Participant number in the project	099012188 4
Funding % for 2017 (article 18)	100%	Method based on actual indirect costs?	No
		Method based on flat rate of 30 %?	Yes

1- Declaration of eligible costs (in €)

	Type of activity				TOTAL (A+B+C+D)
	Direct (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	77,375.00	10,207.00	0.00	0.00	87,582.00
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	33,497.00	0.00	0.00	0.00	33,497.00
Subtotal direct costs	110,872.00	10,207.00	0.00	0.00	121,079.00
Indirect costs	22,214.44	2,049.44	0.00	0.00	24,263.88
Total	133,086.44	12,256.44	0.00	0.00	145,342.88
Maximum IMI JU contribution	98,964.69	12,345.44	0.00	0.00	111,310.13
Requested IMI JU contribution					112,218.00

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 17. Or did the project generate any income which could be considered a receipt according to Art. 11.15 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. 11.15 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. 8.13.2 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 writer attached to this financial statement according to Art. 11.4.4 of the grant agreement? (The agreement to provide a certificate on the financial statements must be valid for those beneficiaries that declare personnel and direct costs of the costs of a certified methodology approved by the European Commission after the Research Infrastructure Programme in accordance with Art. 11.13.2 of the grant agreement, except for the flat rate for indirect costs 11.4.3 of the grant agreement.)

No

Name of the beneficiary: _____ Cost of indirect costs (in €): 0.00

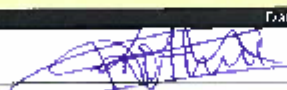
6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to reach 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 clause) 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;
- the financial supporting documentation to verify the information hereby declared, will be made available at the request of the IMI JU and in the event of a successful proposal, if applicable (cf. section 11.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors and/or the responsible institutions.

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. 11.15 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	Femke Kothuis
	Date & Signature
	
	31/08/2017

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	01/08/2016	Is this an adjustment to a previous statement?	No
To	31/07/2017		

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. 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.)

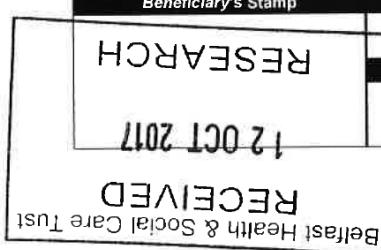

No

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
	Sarah Kathleen O'Brien
	Date & signature
	
	13/10/17

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

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

Project nr Project Acronym	116721 ABC Programme	Funding scheme	IMI Research Project
Period from To	01/09/2016 31/07/2017	Is this an agreement to a research network?	No
Legal Name Organization short Name	Fraunhofer-Gesellschaft zur Förderung der angewandten Forschung e.V. Fraunhofer ITEM	Participant Identity Code (PIC) Participant number in the project	90004000 6
Funding % for RTD activities (A)	76 %	Indirect Costs Method based on actual indirect costs?	Yes
		Method based on flat rate of 20 %?	No

1- Declaration of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	736.31	0.00	0.00	0.00	736.31
S. the contracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	0.00	0.00	0.00	0.00	0.00
S. b total direct costs	736.31	0.00	0.00	0.00	736.31
Indirect costs	719.87	0.00	0.00	0.00	719.87
Total	1,478.28	0.00	0.00	0.00	1,478.28
Maximum IMI JU contribution	1,107.21	0.00	0.00	0.00	1,107.21
Requested IMI JU contribution					1,107.21

2- Declaration of receipts

2a) Did you receive any financial contribution from an EPPMA 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. 11.18 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. 11.13.1 of the grant agreement?

Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. 11.7.2 of the grant agreement?

Yes
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 of the grant agreement? This certificate is a contract or an internal document that contains the financial data and the resources that have been used and the costs of a specific methodology approved by the European Commission with the Seventh Framework Programme in accordance with Art. 11.7.2 of the grant agreement, or approved by the managing entity, Art. 11.4 of the grant agreement.

Name of the auditor



Cost of the certificate (in €)

No
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. 11.18 and 11.14 of the grant agreement and Article 7 (special clause) of the grant agreement;
- the receipts declared above are the only financial contributions from EPPMA companies, financial institutions 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 court of an audit by the IMI JU and/or, if applicable (for section E.3 of Annex II), by the Commission (including OLAF) and the Court of Auditors under the authorized representatives;
- the information 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) Authorized to sign this Financial Statement
	Simon Jägermann
	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 To	01/08/2016 31/07/2017	Is this an adjustment to a previous statement?	No
Legal Name Organisation short name	RUGS UNIVERSITEIT GRONINGEN RUG	Participant Identity Code (PIC) Participant number (if the project)	939885782 7
Funding % for R&D activities (A)	75%	Indirect Costs Method based on actual indirect costs? Method based on flat rate of 20%?	No Yes

1. Breakdown of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTO (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	51,497.90	0.00	0.00	0.00	51,497.90
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	8,048.60	0.00	0.00	0.00	8,048.60
Subtotal direct costs	60,047.50	0.00	0.00	0.00	60,047.50
Indirect costs	12,008.50	0.00	0.00	0.00	12,008.50
Total	72,057.00	0.00	0.00	0.00	72,057.00
Maximum IMI JU contribution	54,042.75	0.00	0.00	0.00	54,042.75
Requested IMI JU contribution					54,042.75

2. Declaration of receipts

2a) Did you receive any financial contribution from an EPPA 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 71, or did the project generate any income which could be considered a receipt according to Art. 11.15 of the grant agreement?
If yes, please mention the amount (in €)

No
0.00

3. Declaration of interest yielded by the use of funding (only for the managing entity of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. 11.15 of the grant agreement?
If yes, please mention the amount (in €)

No
0.00

4. Certificate on the methodology

Do you declare to manage 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 is applicable in relation to the financial statements that are subject to audit according to the relevant provisions on indirect costs on the basis of a certified methodology approved by the European Commission within the European Framework Programme in accordance with Art. 11.13.2 of the grant agreement, or subject to the Commission audit, 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 the transfer

We do so 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. 11.15 and 11.14 of the grant agreement *and* Article 7 (special clause) of the grant agreement;
- the receipts declared above are the only financial contributions from EPPA 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 verify 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 (see section 11.2 of Annex B), by the Comptroller (including OLAF) and the Court of Auditors under the authorized 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. 11.15 of the grant agreement.

Beneficiary's Name	Name of the Person(s) Authorized to sign this Financial Statement
	A. Ebbes
	Date & Signature
	14-9-2017



university of
 groningen
 faculty of science
 and engineering

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

Project ID	116721	Funding scheme	IMI Research Project
Project Acronym	ABC Programme		
Period from	01/01/2015	Is this an adjustment to a previous statement?	Adjustment to period 1
In	31/07/2018		
Legal Name	SERVICIO MADRILEÑO DE SALUD	Participant Member Code (PIC)	P92-481887
Organisational Unit Name	SERMAS	Participant number in the project	8
Funding % for RTE activities (A)	73 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 21.5%?	Yes

1- Description of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTE (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	1,085.61	0.00	0.00	0.00	1,085.61
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	0.00	0.00	0.00	0.00	0.00
Subtotal direct costs	1,085.61	0.00	0.00	0.00	1,085.61
Indirect costs	219.52	0.00	0.00	0.00	219.52
Total	1,305.13	0.00	0.00	0.00	1,305.13
Maximum IMI JU contribution	953.65	0.00	0.00	0.00	953.65
Requested IMI JU contribution					953.65

2- Declaration of receipts

2a) Did you receive any financial contribution from an EPPA 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 social clause 11, or did the project generate any income which could be considered a receipt according to Art. 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. 16 of the grant agreement?

If yes, please mention the amount (in €)

No
0.00

4- Certificate on the methodology

Do you apply foreign personnel costs according to Art. 11.10.2 of the grant agreement?

Is this a certified methodology provided by an independent auditor and approved by the European Commission according to Art. 11.2 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. 11.4.1 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that receive personnel and indirect costs at the basis of a certified methodology approved by the European Commission under the Seventh Framework Programme according to Art. 11.2.2 of the grant agreement, except for the final reporting period, Art. 11.4.6 of the grant agreement.)

No

Net cost 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 to the definition of eligible costs specified in Art. 11.10 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 EPPA 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. 16 of the grant agreement;
 - the overall supporting documentation to justify the information hereby declared will be made available at the request of the IMI JU and in the event of an audit by the IMI JU auditor, if applicable (in section 11.3 of Annex II), by the Commission (including OIAF) and the Court of Auditors and/or the supervising institutions;
- 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. 16 of the grant agreement.

Printed Name of Signatory	Name of the Person(s) Authorised to sign this Financial Statement
	JOSE IGNACIO FLORES NICOLAS
	Date & signature
	7 th September, 2017 



IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

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

Project nr Project Acronym	116711 IABC Programme	Funding scheme	IMI Research Project
Started from To	01/08/2016 31/07/2017	Is this an adjustment to a previous statement?	No
Legal Name Organisation short Name	Universitat Zehemhuis Antwerpen UZA	Participant Identity Code (PIC) Participant number in the project	094727896 9
Funding % for RTO-activities (a)	75 %	Indirect Costs Method based on actual indirect costs? Method based on flat rate of 20 %?	No Yes

1- Description of eligible costs (in €)

	Type of Activity				TOTAL (A+B+C+D)
	RTO (A)	Management (B)	Training (C)	Other (D)	
Personnel costs	30,219.50	38,683.64	0.00	0.00	70,003.14
Travel and meeting	0.00	0.00	0.00	0.00	0.00
Other direct costs	17,490.17	0.00	0.00	0.00	17,490.17
Sub total direct costs	47,812.47	38,683.64	0.00	0.00	87,496.11
Indirect costs	9,662.89	7,808.71	0.00	0.00	17,499.26
Total	57,374.06	47,492.35	0.00	0.00	104,896.21
Minimum IMI JU contribution	43,031.22	47,492.35	0.00	0.00	90,561.47
Requested IMI JU contribution					90,561.47

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 of the financial statements provided by an independent auditor attached to this financial statement according to Art. II.4.4 of the grant agreement? (The responsibility to provide a certificate on the financial statements shall be a duty of those beneficiaries who receive personnel and hardware costs on the basis of a certified methodology approved by the European Commission under the Seventh Framework Programme in accordance with Art. II.13.2, third paragraph, second to the first sentence, from Art. II.4.4 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 as specified in Art. II.13 and II.14 of the grant agreement and Article 7 (special clause) 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 I/we have declared. It will be made available at the request of the IMI JU and in the event of an audit by the IMI JU auditor, if applicable (cf section II.3 of Annex III), by the Commissioner (including OLAF) and the Court of Auditors and/or their outsourced 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 name	Name of the Person(s) Authorised to sign this Financial Statement
Universiteit Zehemhuis Antwerpen Dienst Administratie & Financien Wilrijkstraat 10 2050 EDEGEM	Daisy Van Weghem Date & signature 25/08/17

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	01/08/2016	Is this an adjustment to a previous statement?	No
To	31/07/2017		

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	182,652.08	497.05	0.00	0.00	183,149.13
Subcontracting	147,646.84	0.00	0.00	0.00	147,646.84
Other direct costs	41,881.84	0.00	0.00	0.00	41,881.84
Sub-total direct costs	372,180.76	497.05	0.00	0.00	372,677.81
Indirect costs	44,906.78	99.41	0.00	0.00	45,006.19
Total	417,087.54	596.46	0.00	0.00	417,684.00
Maximum IMI JU contribution	312,816.66	596.46	0.00	0.00	313,412.12
Requested IMI JU contribution					313,412.12

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.)


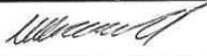
Yes

Name of the auditor	Henderson Loggie	Cost of the certificate (in €)	1,509.39
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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	
	Michael Hassall	
	Date & signature	
	04/10/2017	

DUNDEE

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	01/08/2016	Is this an adjustment to a previous statement?	No
To	31/07/2017		

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
		Indirect Costs 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
	Philippe Leconte
	Date & signature
	23/08/2017

DE 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 financing entity (special clause 5) who must use the form for beneficiaries

Participant ID	11572	Participant Name	IMI Research Project
IMRC Programme			
Start Date	01/08/2016	Is this an adjustment to previous statements?	No
End Date	31/07/2017		
Participant Address	Université de Poitiers	Participant Contact Person	
Participant Contact Email	UP	Participant Contact Phone	44
Participant Contribution %	75 %	Participant Contribution Type	No
			Yes

1- Declaration of eligible costs (in €)

	2016	2017	Total	2016	2017	Total
Personnel costs	0.00	0.00	0.00	0.00	0.00	0.00
Equipment	0.00	0.00	0.00	0.00	0.00	0.00
Other direct costs	0.00	0.00	0.00	0.00	0.00	0.00
Administrative costs	0.00	0.00	0.00	0.00	0.00	0.00
Indirect costs	0.00	0.00	0.00	0.00	0.00	0.00
Total	0.00	0.00	0.00	0.00	0.00	0.00
Maximum IMI JU contribution	0.00	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 IMI JU profit generated by IMI JU which could be considered a receipt according to Art. 113 of the grant agreement?
 Yes, please mention it in column 2

No
 0.00

3- Certificate on the method of pay

Do you receive salaries and personal costs according to Art. 112.2 of the grant agreement?
 Is there a certified method of pay (checked by an independent auditor and approved by the European Commission according to Art. 112.2 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 the financial statement according to Art. 112.4 of the grant agreement? (This requirement is specific to projects generated on the revenue basis costs by a financing entity linked to a beneficiary that either has an annual turnover of less than 10 million euros or is controlled by the Commission, in accordance with the Special Financial Regulations applicable under Article 112.2 of the grant agreement, and Article 104 regarding award Art. 112.4 of the grant agreement)

No

Amount of IMI JU contribution

0.00

5- Third party's declaration on its account

We declare on our honour that:

- the costs declared above are directly related to the activities used to attain the objectives of the project and fall within the definition of eligible costs specific in Art. 113 and 114 and Article 113 of special clauses of the grant agreement;
- the financials declared above are the only financial transfers or contributions in kind, free of charge, to a third party and the only income generated by the project with financial proceeds as receipts according to Article 112 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, under the auspices of (as set on 0.8 of Annex II), by the Commission (including OLAF) and the Office of Auditors under their authorized representatives.

Signature of the third party

Laurent ANNE

31/07/17

le directeur général des services

Closed

LEUEN-ANNE



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?	No
To	31/07/2017		
Legal Name	Università degli Studi di Milano	Participant Identity Code (PIC)	999995796
Organisation short Name	UMIL	Participant number in the project	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	16,617.50	5,901.14	0.00	0.00	22,518.64
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	16,617.50	5,901.14	0.00	0.00	0.00
Indirect costs	3,323.50	1,180.23	0.00	0.00	4,503.73
Total	19,941.00	7,081.37	0.00	0.00	27,022.37
Maximum IMI JU contribution	14,955.75	7,081.37	0.00	0.00	22,037.12
Requested IMI JU contribution					22,037.12

2- Declaration of receipts

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

If yes, please mention the amount (in €)

No

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

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

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

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

No


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 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 Gianluca Gaetano Vago
	Date & signature 28 AGO. 2017 IL RETTORE Gianluca Vago

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	01/08/2016	Is this an adjustment to a previous statement?	No
To	31/07/2017		

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	969.12	0.00	0.00	0.00	969.12
Sub-total direct costs	969.12	0.00	0.00	0.00	969.12
Indirect costs	193.82	0.00	0.00	0.00	193.82
Total	1,162.94	0.00	0.00	0.00	1,162.94
Maximum IMI JU contribution	872.21	0.00	0.00	0.00	872.21
Requested IMI JU contribution					872.21

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
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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. 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, 26 20122 MILANO	dr Simona Girolodi
	Date & signature
3 1 AGO. 2017	IL DIRETTORE GENERALE (Dott.ssa Simona Girolodi)

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?	No
To	31/07/2017		

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. 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.)


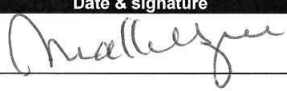
No

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 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
	Muriel MALBEZIN
	Date & signature
	26/09/2017 

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

Project or Project Acronym	126721 uABO Programme	Funding scheme	IMI Research Project
Period from To	01/09/2018 31/07/2019	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	888376426 90
Funding % for RTD activities (A)	78 %	Indirect Costs Method based on actual indirect costs? Method based on flat rates 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	4.590,82	0,00	0,00	0,00	4.590,82
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	4.590,82	0,00	0,00	0,00	4.590,82
Indirect costs	818,12	0,00	0,00	0,00	818,12
Total	5.408,94	0,00	0,00	0,00	6.599,74
Maximum IMI contribution	4.121,66	0,00	0,00	0,00	4.121,66
Requested IMI contribution					4.121,66

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 benefits or contributions in kind, free of charge, from third parties (not in a confidential under special clause 1), or did the project generate any income which should 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 use of equity of the IMI JU funds)

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
0,50

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. 11.12 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 of the grant agreement? (This requirement covers a certificate on the financial statements submitted for the year 2018 for all direct personnel and indirect costs in the case of a certified methodology approved by the European Commission under the Horizon Framework Programme in accordance with Art. 11.13.2 of the grant agreement, except for the first receiving period, Art. 11.5 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 definitions of eligible costs specified in Art. 11.14 and 11.14 of the grant agreement and Article 7 (specialised rules) of the grant agreement;
- the receipts declared above are the only financial contributions from EFPIA companies, financial benefits 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, if not otherwise available at the request of the IMI JU and in the event of an audit by the IMI JU and/or if applicable (if section 11.5 of Annex III) by the Commission (including OIAF) and the Court of Auditors under their respective representations.

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
	Dr. rer. Göbel Date & Signature 22.09.2019

Medizinische Hochschule Hannover
Dietrich-Hildebrand
Carl-Neuberg-Straße 1 • 30625 Hannover

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

Project ID Project acronym	149721 IABC Programme	Funding scheme	IMI Research Project
Period from To	01/08/2016 31/07/2017	Is this an adjustment to a previous submission? <input type="checkbox"/> No	
Legal Name Organisation short name	University of Antwerp UANTWERP	Participant Identity Code (PIC)	999902870
Funding % for RTD activities (%)		75%	Indirect costs Method based on actual indirect costs? <input type="checkbox"/> No Method based on flat rate of 80%? <input type="checkbox"/> Yes

1- Declaration of eligible costs (Art 6)

	RTD (A)	Management (B)	Training (C)	Other (D)	TOTAL (A+B+C+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
Substantial indirect 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 EFPA 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 second clause 11, or did the project generate any income which could be considered a receipt according to Art. 11.10 of the grant agreement?
 if yes, please mention the amount (in €)

No
 0.00

3- Declaration of interest vs. cost (by the pre-financing only for the financing stage of the IMI JU funding)

Did the pre-financing you received generate any interest according to Art. 11.10 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. 11.2 of the grant agreement?

No

Is there a certified methodology provided by an independent auditor as approved by the European Commission according to Art. 11.10 of the grant agreement?

No

5- Certificate on the financial statements

Do you agree to provide on the financial statements provided by an independent auditor attached to this financial statement according to Art. 11.10 of the grant agreement? (The beneficiary is responsible to make a copy of the financial statements and to submit for those beneficiaries tax clearance, provision and indirect costs or % costs of essential infrastructure approved by the European Commission in the Event Framework Reference Agreement in accordance with Art. 11.10 of the grant agreement, concerning the reporting period of the grant agreement.)

No

Name of the auditor

Cost of the certificate (in €)

0.00


6- Beneficiary's declaration on its budget

On behalf of our Income Pool:

- 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. 11.1) and 11.14) of the grant agreement and Article 7 (special criteria) of the grant agreement
- the receipts declared above are the only financial contributions from EFPA 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. 11.10 of the grant agreement
- there is full supporting documentation to justify the information hereby declared. It will be made available on the request of the IMI JU and in the event of an audit by the IMI JU or other competent authorities (in particular the Commission (including DG-RES) and the Court of Auditors) and/or the authorised representatives.

ONLY FOR THE IMI JU ENTITY

- the interest declared above is the only interest payable by the beneficiary which falls within the definition of Art. 11.10 of the grant agreement.

Beneficiary's Name	University of Antwerpen	Name of the Person(s) Authorized to sign this Financial Statement	Prof. H. Gommers of Mr. G. Meunier
		Date & signature	

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	01/08/2015 31/07/2017	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	989066507 17
Funding % for RTD activities (A)	76 %	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	78,874.68	0.00	0.00	0.00	78,874.68
Subcontracting	0.00	0.00	0.00	0.00	0.00
Other direct costs	1,894.64	0.00	0.00	0.00	1,894.64
Subtotal direct costs	80,769.32	0.00	0.00	0.00	80,769.32
Indirect costs	8,095.88	0.00	0.00	0.00	8,095.88
Total	88,865.20	0.00	0.00	0.00	88,865.20
Maximum IMI JU contribution	27,422.39	0.00	0.00	0.00	27,422.39
Requested IMI JU contribution					27,422.39

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 7.1, or did the project generate any income which could be considered a receipt according to Art. 6.15 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. 6.18 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. 6.13.2 of the grant agreement?

Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. 6.13.2 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. 6.4.4 of the grant agreement? (This 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 Research Framework Programme as approved with Art. 6.13.2 of the grant agreement, issued by the IMI regarding period Art. 6.4.5 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. 6.13 and 6.14 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. 6.15 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 (cf section III 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. 6.18 of the grant agreement.

Beneficiary's Stamp	Name of the Person(s) Authorized to sign this Financial Statement
ROYAL BROMPTON & HAREFIELD NHS FOUNDATION TRUST	Ms Laura Forrest
	Date & signature
	1/9/17 <i>Laura Forrest</i>

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

Project or Project Acronym	115721 IADC Programme	Funding scheme	IMI Research Project
Period from	01/08/2016	Is this an adjustment to a previous statement?	No
To	31/07/2017		
Legal Name	FUNDACIO CLINIC PER A LA RECERCA BIOMEDICA	Participant Identity Code (PIC)	985477020
Organisation short Name	FCRR	Participant number in the project	11
Funding % for RTD activities (A)	25 %	Indirect Costs	
		Method based on actual indirect costs?	No
		Method based on flat rate of 26 %?	Yes

1- Declaration of eligible costs (in €)

	Type of Activity				Other (D)	TOTAL (A+B+C+D)
	RTD (A)	Management (B)	Training (C)			
Personnel costs	3,050.09	0.00	0.00	0.00	0.00	3,050.09
Subcontracting	0.00	0.00	0.00	0.00	0.00	0.00
Other direct costs	0.00	0.00	0.00	0.00	0.00	0.00
Subtotal direct costs	3,050.09	0.00	0.00	0.00	0.00	3,050.09
Indirect costs	610.02	0.00	0.00	0.00	0.00	610.02
Total	3,660.11	0.00	0.00	0.00	0.00	3,660.11
Maximum IM JU contribution	2,746.08	0.00	0.00	0.00	0.00	2,746.08
Requested IM JU contribution						2,746.08

2- Declaration of receipts

2a) Did you receive any financial contribution from an EFPMA company? No

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 7a, or did the project generate any income which could be considered a receipt according to Art. II.18 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 IM JU fund(s))

Did the pre-financing you received generate any interest according to Art. II.18 of the grant agreement? No

If yes, please mention the amount (in €)

4- Certificate on the impartiality

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

Is there a cost sheet (certificate) 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 certificate is attached as a table in the financial statements sheet to be filled for basic beneficiaries but does not concern personnel costs on the basis of a cost sheet submitted as evidence approved by the European Commission under the Special Financial Requirements as referred to in Art. II.13.2 of the grant agreement, except for the flat rate according to Art. II.4.4 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 herein are directly related to the resources used to attain the objectives of the project and fall within the definition of eligible costs specified in A. I. II.15 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 EFPMA 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.18 of the grant agreement;
- these (a-c) supporting documents submitted to justify the information hereby declared, shall be made available at the request of the IM JU and in the event of an audit by the IM JU under the applicable provisions of Annex I, by the Commission (including OLAF) and the Court of Auditors under their authorised representations.

ONLY FOR THE MANAGING ENTITY

- the interest costs declared are 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
	Rosa Vilavella Gasull, Legal Representative
	Date & signature
	 29.08.2017

IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

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

Project ID	115721	Contract scheme	IMI Research Project
Project Activity	IABC Programme		
Project from To	01/08/2016 31/07/2017	Is this an adjustment to a previous statement?	No
Legal Entity	Papworth Hospital NHS Foundation Trust	Financial Entity Code (FEC)	95146895
Organisation short name	PAP	Period and number in this project	19
Funding ratio for RTO activities	75 %	Indirect Costs	
		Neither based on a flat rate (Annex I)	No
		Neither based on flat rate of 20 %	Yes

1. Declaration of eligible costs (in €)

	RTO (a)	Non RTO (b)	Indirect costs (c)	Other (d)	TOTAL (a-b+c+d)
Personnel costs	29,087.73	0.00	0.00	0.00	29,087.73
Sub-contracting	0.00	0.00	0.00	0.00	0.00
Operational costs	434.99	0.00	0.00	0.00	434.99
Materials and goods	29,422.23	0.00	0.00	0.00	29,422.23
Travel costs	8,906.48	0.00	0.00	0.00	8,906.48
Total	28,426.86	0.00	0.00	0.00	28,426.86
Maximum IMI JU contribution	21,320.21	0.00	0.00	0.00	21,320.21
Requested IMI JU contribution					21,320.21

2. Declaration of receipts

2a) Did you receive any financial contribution from an ERMIA 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 partner of another special clause T1, 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 liability 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. 11.3.2 of the grant agreement?
Is there a certified methodology provided by an independent auditor and approved by the European Commission according to Art. 11.3.2 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 of the grant agreement? (This 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 under the Seventh Framework Programme in accordance with Art. 11.3.2 of the grant agreement, except for the final reporting period Art. 11.4.3 of the grant agreement)

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 fulfil the objectives of the project and fall within the definition of eligible costs, as defined in Art. 11.3 and 11.14 of the grant agreement and Article 7 (special clause) of the grant agreement;
- the receipts declared above are the only financial contributions from ERMIA 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 (for section 11.3 of Annex II), by the Commission (including CLAF) and the Court of Auditors and/or their authorised representatives.

ONLY FOR THE MANAGING ENTITY

- the interest declared above is the only interest paid 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
	Sophie Jackson
	Date & Signature
	 14-09-17

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

Project nr (Project Acronym)	111721 IABC Programme	Funding scheme	IMI Research Project
Period from To	01/01/2016 31/12/2017	Is this an adjustment to a previous declaration?	No
Legal Name Organisation short Name	CRASMUS UNIVERSITEIT MEDISCH CENTRUM ROTTERDAM CMC	Participant Identity Code (PIC) Participant number in the project	99496424 20
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	71.368,60	0,00	0,00	0,00	71.368,60
Sub-contracting	0,00	0,00	0,00	0,00	0,00
Other direct costs	927,38	0,00	0,00	0,00	927,38
Sub-total direct costs	72.295,98	0,00	0,00	0,00	72.295,98
Indirect costs	14.463,20	0,00	0,00	0,00	14.463,20
Total	86.759,18	0,00	0,00	0,00	86.759,18
Maximum IMI JU contribution	65.064,39	0,00	0,00	0,00	65.064,39
Requested IMI JU contribution					65.064,39

2- Declaration of receipts

2a) Did you receive any financial contribution from an ERPIA 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. 1.18 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- Cost/Trade on the methodology

Do you declare average personnel costs according to Art. 1.13.2 of the grant agreement?
Is there a certified methodology followed by an independent auditor and approved by the European Commission according to Art. 1.13.2 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. 1.14.4 of the grant agreement?
Did you declare average personnel costs on the basis of a certified methodology approved by the European Commission according to Art. 1.13.2 of the grant agreement?

No
0,00

Name of the auditor: _____ Cost of the certificate (in €): 0,00


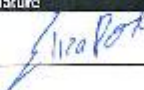
6- Beneficiary's declaration on its honour

We declare on our honour that:

- the costs declared above are directly related to the resources used to attain the objectives of the programme IMI within the definition of eligible costs specified in Art. 1.13 and 1.14 of the grant agreement and Article 7 (general clause) of the grant agreement;
- the receipts declared above are the only financial 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. 11.18 of the grant agreement;
- these declarations are made 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 or other, if applicable (for section 11.2 of Annex I), 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. 1.18 of the grant agreement.

 PO Box 2040 3000 CA Rotterdam	Name of the Person(s) Authorised to sign this Financial Statement	
	E. Rozing	
	Date & signature	
	31-08-2017 	

Summary Financial Report - Research

Project acronym	LABC Programme	Project ref	180721	Reporting period from	6/10/2016	to	31/07/2017	DATE of this report	13/10/2017
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Participant site	Type of participant (industry/ ERPA/ mixed to participant)	E-21 Party - mixed to participant	Adult (months)	Organisation Short Name	Type of activity						Receipts			For ERPA companies								
					RTD (A)	Management (B)	Training (C)	Other (D)	Total (E)	Max (F)	Total (G)	Max (H)	Financial (I)	Other (J)	Total (K)	Requested (L)	ERPA eligible (M)	ERPA financial (N)	TOTAL (O)			
	(A1)	(A2)	(B1)	(B2)	(C1)	(C2)	(D1)	(D2)	(E1)	(E2)	(F1)	(F2)	(G1)	(G2)	(K1)	(K2)	(K3)	(L1)	(M1)	(N1)	(O1)	
1	ERPA		No	NEV																		
2	Industry		No	QIB	234238701	179629716	16248222	0.00	0.00	46245.20	162482.20	225129024	146574600	6727920	0.00	6727962.8	1062746.00	238000.00	82260.00	310260.00		
2	Industry		Yes	QIB	62037846	47100000	-28000	0.00	0.00	-28000	-28000	-22100000	4720000	0.00	0.00	0.00	-1720000					
3	ERPA		No	Bulba																		
4	Industry		No	UMU	1522840	9550000	122440	0.00	0.00	122440	122440	1465440	1122020	0.00	0.00	0.00	912150					
5	Industry		No	BRCT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
6	Industry		No	Facile-ITM	140620	110721	0.00	0.00	0.00	0.00	0.00	140620	110721	0.00	0.00	0.00	140721					
6	Industry		Yes	Facile-ITM	6971	6720	0.00	0.00	0.00	0.00	0.00	6971	6720	0.00	0.00	0.00	6720					
7	Industry		No	M40	726900	644670	0.00	0.00	0.00	0.00	0.00	726900	644670	0.00	0.00	0.00	644670					
8	Industry		No	BRIMU0	462900	242264	0.00	0.00	0.00	0.00	0.00	462900	242264	0.00	0.00	0.00	242264					
8	Industry		Yes	BRIMU0	124170	80800	0.00	0.00	0.00	0.00	0.00	124170	80800	0.00	0.00	0.00	80800					
9	Industry		No	USA	572900	432822	4762020	0.00	0.00	4762020	4762020	1640021	902947	0.00	0.00	0.00	902947					
10	Industry		No	UMCU0	4176924	2128000	59000	0.00	0.00	59000	59000	4176924	2128000	0.00	0.00	0.00	2128000					
10	Industry		Yes	UMCU0	167020	112820	0.00	0.00	0.00	0.00	0.00	167020	112820	0.00	0.00	0.00	112820					
11	Industry		No	BRIMU0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00					
1101	TRAI Pdg	HEBIM	No	UP	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00					
12	Industry		No	UM	162900	142870	700027	0.00	0.00	700027	700027	210227	220712	0.00	0.00	0.00	220712					
1201	TRAI Pdg	UM	No	REC201	11824	6721	0.00	0.00	0.00	0.00	0.00	11824	6721	0.00	0.00	0.00	6721					
13	Industry		No	NEL	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00					
14	Industry		No	M41	52074	42120	0.00	0.00	0.00	0.00	0.00	52074	42120	0.00	0.00	0.00	42120					
15	Industry		No	UMTMRP	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00					
16	Industry		No	UM	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00					
1601	TRAI Pdg	UM	No	HEUC000	216744	162900	0.00	0.00	0.00	0.00	0.00	216744	162900	0.00	0.00	0.00	162900					
17	Industry		No	HE17	260010	274220	0.00	0.00	0.00	0.00	0.00	260010	274220	0.00	0.00	0.00	274220					
18	Industry		No	PE10	200011	224600	0.00	0.00	0.00	0.00	0.00	200011	224600	0.00	0.00	0.00	224600					

Milestone supplementary evidence

1. WP4

Milestone M4.3 Site selection and pre-identification complete

Milestone M4.4 First patient first visit in Phase II trial of TIP complete

The following page contains the report from the Phase II trial CRO, ICON, to verify that these have been achieved.



File Note

<input checked="" type="checkbox"/> In-house observation/finding		<input type="checkbox"/> On-site observation/finding	
Investigator Name: NA	Site No.: NA	Eudract No.: 2015-003040-39	IND/IDE No.: NA
Protocol No.: CTBM100G2202	Sponsor: Novartis Pharma		Date: 12 October 2017
Study Name/Protocol Title:			
A randomized, blinded, parallel group, multi-center dose finding study, to assess the efficacy, safety and tolerability of different doses of tobramycin inhalation powder in patients with Non-Cystic Fibrosis Bronchiectasis and pulmonary P. aeruginosa infection			

Observation/Finding
<p><u>Milestones</u></p> <p>This is to document that the following milestones have been achieved:</p> <ul style="list-style-type: none"> Site selection has been completed on 07 December 2016. First Patient Screened has been completed on 02 February 2017.

Action required: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>
If yes, please describe (Include Action Plan Date / Action Due Date):
Action completed: YES <input type="checkbox"/> NO <input type="checkbox"/>
If no, please describe (Include Completion Date):

Signature			
Name	Function	Signature	Date
Jens Lachmann	Project Manager	Lachmann, Jens	
Digitally signed by Lachmann, Jens DN: dc=com, dc=iconcr, ou=ICR, ou=Users, cn=Lachmann, Jens, email=Jens.Lachmann@iconplc.com Date: 2017.10.12 16:33:13 +02'00'			

