



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

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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 deviations<sup>1</sup>;
- has failed to achieve critical objectives and/or is not at all on schedule<sup>2</sup>

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: Signature of the Coordinator: S David Digitally signed by Hughes David DN: dc=com, dc=novartis, ou=people, ou=60, serialNumber=1370161, cn=Hughes David Date: 2017.10.12 01:55:47 +0200'

## **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 - Packag e Numbe r	Milestone/ Deliverable (number and short title)	Date Due (Annex I- descriptio n of work)	Completed (Yes/Not yet/Partially)	Dissemin . level <sup>1</sup>	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

<sup>&</sup>lt;sup>1</sup> 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 BAL30072completed. 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	СО	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  $\beta$ 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  $\beta$ 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 19the 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.

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 <sup>th</sup> July 2017/ World BE conference, Milan	Scientific community, patients organisations

## 3.2 Key dissemination activities

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	Pre-clinical development of BAL30072 as inhalation therapy: formulation development and device selection. <b>Work</b> <b>Package 2 is no longer active following</b> <b>the termination of BAL30072-related</b>	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). <i>WP4A</i> <i>has been removed due to the termination</i> <i>of BAL30072 related activities</i>	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

Del. No.	Deliverable name		WP No.	Natur	e	Delivery date
D6.7	Selected sites involved in LCI measuremer Phase II study set up and trained	nt for BE	6	(	D	M26
D4.2	Phase II trial of TIP in BE patients (abbrevi of key outcomes).	ated report	4	I	२	M39
D5.4	Annual data reports.		5	-	3	M13, M25, M37, M49, M60, M77
D5.5	Peer reviewed publications and abstracts.		5	I	3	M13, M25, M37, M49, M60, M77
D6.4	NGS microbiome analysis of samples colle Phase II TIP dose finding study and compa exploratory molecular and conventional microbiological endpoints.		6	1	२	M33
D6.9	Interim analysis (Phase II TIP dose finding the responsiveness of LCI endpoint in com conventional FEV <sub>1</sub> endpoint and CT param	nparison to	6	F	२	M33
D6.11	Final Analysis of Phase II TIP CT outcome r Cross sectional and longitudinal comparise related outcome measures to spirometry outcome measures.	on of CT	6	I	२	M33
D6.15	Analysis of sputum inflammatory biomark collected in Phase 2 TIP dose finding study comparison with conventional and other e endpoints	y and	6	1	3	M33
Milestone No.	Milestone name	WPs involved	Expec delivery		Me	ans of verification
M4.5	Completion of enrolment in Phase II trial of TIP	4	M2 <sup>-</sup>	7	CR	O report received
M4.6	Last Patient last visit in the Phase II TIP study	4	M3	5	CR	O report received
M5.5	Enrolment of 4000 patients from at least 20 EU Countries.	5	M2	6	Re	gistry data reports
M6.1	Exploratory molecular endpoints to measure changes in composition of the airway microbiome/resistome determined.	6	M3	5		stracts at scientific erences and journa article
M6.5	Validation of LCI as a meaningful secondary exploratory outcome measure in Phase II TIP BE study (WP 4B).	6	M3	5		stracts at scientific erences and journa article

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

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	Responsib le Participant	Action to be taken	Due Date
WP1 Reduced project delivery time in WP7 & WP8 due to delay in development of the new DoW.	Η	Η	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	Μ	Close collaboration with CRO for sites selection and initiation	NVS/QUB/P AP/RBHT/U NIVDUN/U MIL/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	Η	Η	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	Н	Н	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	Н	L	Steps being taken to moderate recruitment in the UK and enhance recruitment elsewhere	UoD	As described	M28
WP5 Over-recruitment	Μ	Μ	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	Η	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	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

		ANNEX V - F	ORM C		
F	NANCIAL STATE	MENT - to be f	illed in by each <i>ben</i> e	ficiary	
Project nr	115		Funding scheme 🔤	iMI Research	Project
Project Acronym	iABC Pro	gramme			
Period from	01/08/2015		Is this an adjustment to a	previous statement?	Adjustment to period 1
То	31/07/2016			-	
Legal Name	The Queen's Unit	versity of Belfast	Participant Identity	y Code (PIC)	999992013
Organisation short Name	QL	B	Participant number	is the project	2
			Indirect Co	and the second	
Funding % for RTD acti	vities (A)	75 %	Method based on actual in Method based on flat rate	Contraction of the second s	No Yes
1-Declaration of eligible costs (in 6	aa				
	RTD (A)	Ty; Management (B)	e of Activity Training (C)	Other (D)	TOTAL (A+B+C+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 Sub-total direct costs	-196,213.33 -191,495.81	-272.13	0.00	0.00	-196,485.46 -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?		[	No
If yes, please mention the amount				[	0.00
2b) Other receipts Did you receive any financial transi or from a participant under special				tered a receipt	No
according to Art. II:16 of the grant i		ojoot generale any n			
				1000 C 1000 C 1000	
If yes, please mention the amount					0.00
If yes, please mention the amount	(in €)	nly for the managing	entity of the IMI JU funding)	ſ	0.00
	(in €) <u>y the pre-financing</u> (or			Ē	0.00 No
If yes, please mention the amount 3- Declaration of Interest yielded by	(in €) <u>y the pre-financing</u> (or generate any interest a			Ē	No
If yes, please mention the amount of <u>3- Declaration of Interest yielded by</u> Did the pre-financing you received If yes, please mention the amount of	(in €) <u>y the pre-financing</u> (or generate any interest a			[	No
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#### IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

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TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Partner 4 Universit	itair Medisch Centrum U	trecht (UMC	U)
Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources
	Personnel direct costs	€ 88.182	<ul> <li>This costs are only the hours of all project staff;</li> <li>1 PI, 1 PostDoc,, 1 Researcher, 1 Research Technician</li> </ul>
	Subcontracting [if foreseen in Description of Work]	€0	
	Other direct costs	€ 1.095	<ul> <li>This costs include travel and benchfee 2016 and 2017;</li> <li>Hotel, flight, Basel 18-05-2017 (M. Ekkelenkamp)</li> <li>Hotel, flight, Londen 03-04-17 (M. Ekkelenkamp)</li> <li>Hotel, flight, Milan 05-07-17 (M. Ekkelenkamp)</li> </ul>
	Consumables [if applicable]	€ 32.002	€90k WGS
	Equipment depreciation [if applicable]	€0	depreciation of important equipment (provide detail)
	Hardware/Software/licence	€0	
	Indirect costs	€ 24.255,80	e.g. 20% flat rate, actual indirect costs (€ 121.279*0,20)
TOT	AL COSTS	€ 145.534,80	
Budget	for the period	€ 112.213,20	
D	eviation	€ 33.321,60	

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

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING				
Partner no. 6	Fraunhofer-Gesellsch	aft   Period 1 A	djustment	
Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources	
WP2	Personnel direct costs	564,71	Post-calculation of personnel hourly rates 2016.	
	Subcontracting [if foreseen in Description of Work]	0,00		
	Other direct costs	0,00		
	Indirect costs	332,97	Actual indirect costs linked to personnel costs.	
TOTAL COSTS		1.476,28		
Budget	for the period			
D	eviation			

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				
WP2	Personnel direct costs	736,31	Salaries of 1 scientist for 0.08 PM.		
	Subcontracting [if foreseen in Description of Work]	0,00			
	Other direct costs	0,00			
	Indirect costs	739,97	Actual indirect costs based on personnel costs.		
TOTAL COSTS		1.476,28			
Budget for the period					
D	eviation				

Dorthor 7 Diikouni	waraitait Craningan (DLC	<u> </u>	
Partner 7 – Rijksuni	iversiteit Groningen (RUG	)	
Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources
2 2 2 2	Personnel direct costs	25691.14 10436,40 1330.88 14039,48	Salary postdoc 6 pm Salary technician 2.8 pm 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 deprecation a 362,3 = 1811: ((Amount 19200, date invoice 29-3- 2016, total deprecation months 53, this period 5) (Months march until july)
	Equipment depreciation [if applicable]	541,98	Dehumidifier-5 months deprecation a 108,40 = 542: ((Amount 5745, date invoice 29-3-2016, total deprecation months 53, this period 5)
	Equipment depreciation [if applicable	4304,09	Demo Discovery TGA-5 months deprecation a 860,8 = 4304: ((Amount 47345, date invoice 18-1-2016, total deprecation months 55, this period 5)
	Equipment depreciation [if applicable	1862,84	Inhaler5 months deprecation a 372,6 = 1863: ((Amount 21609, date invoice30-10-2015, total deprecation 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	
тот	AL COSTS	72056,99	
Budget	for the period	127015	
D	eviation	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 (SERMA	S) ADJUSTMEN	IT PERIOD 1
Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources
WP2	Personnel direct costs	1095.61 €	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)
	Subcontracting [if foreseen in Description of Work]		
	Other direct costs	0.00€	
	Consumables [if applicable]		
	Travel		
	Equipment depreciation [if applicable]		
	Hardware/Software/licence costs		
Indirect costs		219.12 <b>€</b>	e.g. 20% flat rate, actual indirect costs
TO	TAL COSTS	1314.73€	
Budge	t for the period		
I	Deviation		

TABLE	: PERSONNEL AND OTHER MAJOR	COST ITEMS INCL	UDING SUBCONTRACTING
Partner 8 – Servicio	o Madrileño de Salud (SERMA	S) PERIOD 2	
Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources
WP2	Personnel direct costs	34715.53€	PM (Hired personnel cost: María Díez (22,713.39 € = 5PM) + Own- Staff Personnel cost; R.Cantón, MI. Morosini, M.Tato ( <b>12002.14</b> € = <b>2.3</b> PM)
	<b>Subcontracting</b> [if foreseen in Description of Work]		
	Other direct costs	3423,18 €	
WP2	Consumables [if applicable]	2843.41 €	Microwell Plates F96 (204.96 €), Bioflux-48 Microwell Plates (2094.40 €), culture media (215.10 €), immnuno plates (328.95€).
WP2	Travel	579.77 €	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€).
	Equipment depreciation [if applicable]		
	Hardware/Software/licence costs		
	Indirect costs	7627,74€	e.g. 20% flat rate, actual indirect costs
то	TAL COSTS	45766.45 €	
Budge	et for the period		
	Deviation		

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING				
Partner 9 - Universi	tair Ziekenhuis Antwerper	n (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)	
D	eviation	-193 194.95	Total cost – budget for period	

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING					
Participant no.10	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.		
TOTA	L COSTS	€15,512.53			
Budget f	or the period				
De	viation				

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING				
Participant no.1	0 University of Dunc	dee (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 Billigham, 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.	
TOT	AL COSTS	€417,684.00		
Budget	for the period	€		
D	eviation	€		

TABLE: P	PERSONNEL AND OTHER MAJOR	COST ITEMS IN	CLUDING SUBCONTRACTING
Participant 11 Instit	ut National De La Sante Et	De La Reche	rche Medicale (INSERM)
Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources
4	Personnel direct costs		Salary costs for 1 Scientist/Lead Investigator
	<b>Subcontracting</b> [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	0	20% flat rate
TOT	AL COSTS	0	
Budget for the period			
D	Deviation		

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING				
Participant 1101 Ur	niversité de Poitiers (UP)			
Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources	
	Personnel direct costs		Salary costs for 1 Scientist/Lead Investigator	
	<b>Subcontracting</b> [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	0	20% flat rate	
TOTAL COSTS		0		
Budget for the period				
D	eviation			

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	<ul> <li>2.5 M/M effort of Prof. Francesco Blasi:</li> <li>1.84 M/M for activities related to WP4</li> <li>0.66 M/M for activities related to WP1</li> </ul>			
	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			
TOT	TOTAL COSTS					
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.			

Partner 1201 IRCCS	CA' GRANDA OSPEDAL	E 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 <sup>st</sup> patient	€ 28,03	Informed Consent
		€ 60,07	Medical History,BE-Related Medical History, Smoking History, Pulmonary Exacerbations History, Demographics
		€ 28,03	InIcusion/Exclusion
		€ 88,11	Physical Exam
	<u> </u>	€ 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 <sup>nd</sup> patient	€ 28,03	Informed Consent
		€ 60,07	Medical History,BE-Related Medical History, Smoking History, Pulmonary Exacerbations History, Demographics
		€ 28,03	InIcusion/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		

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING         Participant 13 Hospices Civils de Lyon (HCL)						
4	Personnel direct costs		Eg Salary costs for 1Scientist/Lead Investigator			
	<b>Subcontracting</b> [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	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)					
WP4A	Personnel direct costs	4.590,62	1 Technican 0,55 Months, 1 Technican 0,37 Months		
	Subcontracting [if foreseen in Description of Work]	0,00			
	Other direct costs	0,00			
	Consumables [if applicable]	0,00			
	Equipment depreciation [if applicable]	0,00	depreciation of important equipment (provide detail)		
	Hardware/Software/licence costs	0,00			
	Indirect costs	918,12	e.g. 20% flat rate, actual indirect costs		
TOTAL COSTS		5.508,74			
Budget for the period					
Deviation					

TABLE: P	ERSONNEL AND OTHER MAJOR	COST ITEMS IN	CLUDING SUBCONTRACTING
Participant 15 Unive	ersiteit Antwerpen (UANT)	VERP)	
Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources
	Personnel direct costs		Salary costs for 1Scientist/Lead Investigator
	<b>Subcontracting</b> [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	0	20% flat rate
тот	AL COSTS	0	
Budget	for the period		
D	eviation		

TABLE: P	ERSONNEL AND OTHER MAJO	R COST ITEMS IN	CLUDING SUBCONTRACTING
Partner 16 Universit	y 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 [if foreseen in Description of Work]		
	Other direct costs		
	Consumables [if applicable]		
	Equipment depreciation [if applicable]		
	Other: Travel		
	Indirect costs	0	20% flat rate
TOT	AL COSTS	€0	
Budget	for the period		
D	eviation		

TABLE: P	ERSONNEL AND OTHER MAJO	R COST ITEMS IN	CLUDING SUBCONTRACTING		
Partner 1601 NHS L	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	Adam Hill, PI, 1.2PM		
	Subcontracting [if foreseen in Description of Work]				
	Other direct costs				
	Consumables [if applicable]				
	Equipment depreciation [if applicable]				
	Other: Travel				
	Indirect costs	3,502.91	20% flat rate		
TOT	AL COSTS	€21,017.44			
Budget	for the period				
D	eviation				

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Partner 17 Royal Br	ompton & Harefield NHS I	Foundation Tru	ust (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 [if foreseen in Description of Work]		
	Other direct costs		
WP4	Consumables [if applicable]	1,594.64	Consumables for carrying out Lung Clearance Index (LCI) tests for iBEST1 clinical trial
	Equipment depreciation [if applicable]		depreciation of important equipment (provide detail)
	Hardware/Software/licence costs		
	Indirect costs	6,093.86	e.g. 20% flat rate, actual indirect costs
TOT	AL COSTS	36,563.18	
Budget	for the period	32,802.80	
D	eviation	3,760.38	

TABLE: P	ERSONNEL AND OTHER MAJO	R COST ITEMS INC	CLUDING SUBCONTRACTING
PARTNER 18 FUNDACI	O CLINIC PER A LA RECERCA	BIOMEDICA (FC	CRB ) 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	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).
	Subcontracting [if foreseen in Description of Work]	0,00	
	Other direct costs	0,00	
	Indirect costs	114.21	20% flat rate, actual indirect costs
TOT	AL COSTS	685.24	
Budget	for the period		
D	eviation		

TABLE: P	ERSONNEL AND OTHER MAJO	R COST ITEMS INC	LUDING SUBCONTRACTING
PARTNER NO. 18 FUN	DACIO CLINIC PER A LA RECI	ERCA 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	Personnel costs corresponding to Eva Polverino (IP). Tasks developed in the framework of WP4 (0.83 PM).
	Subcontracting [if foreseen in Description of Work]	0,00	
	Other direct costs	0,00	
	Indirect costs	610.02	20% flat rate, actual indirect costs
тот	AL COSTS	3,660.11	
Budget	for the period	4,240.00	
D	eviation	-579.89	

TABLE: P	ERSONNEL AND OTHER MAJOR	COST ITEMS IN	CLUDING SUBCONTRACTING
Participant no. 1801	Hospital Clínic i Provincia	al de Barcelon	a (HCPB)
Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources
	Personnel direct costs		Salary costs for 1Scientist/Lead Investigator
	<b>Subcontracting</b> [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	0	20% flat rate
TOT	AL COSTS	0	
Budget	for the period		
D	eviation		

TABLE: F	PERSONNEL AND OTHER MAJO	R COST ITEMS IN	CLUDING SUBCONTRACTING
Partner 19 Papwort	h Hospital NHS Foundatio	n 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	Dr Haworth's CI time commitment
			Research Nurse Support for WP4 iBEST1 clinical trial
	Subcontracting [if foreseen in Description of Work]		
	Other direct costs		
WP4	Travel	434.50	Dr Haworth travel to the General Assembly meeting held in Milan 7 <sup>th</sup> July 2017
	Consumables [if applicable]		
	Equipment depreciation [if applicable]		depreciation of important equipment (provide detail)
	Hardware/Software/licence costs		
	Indirect costs	5904.45	e.g. 20% flat rate, actual indirect costs
TOT	ALCOSTS	35426.68	
Budget	for the period	2 <sup>nd</sup> Year	
C	Deviation		

TABLE: PERSONNEL AND OTHER MAJOR COST ITEMS INCLUDING SUBCONTRACTING			
Partner 20 Erasmus	s Universitair Medisch Ce	ntrum Rotterd	am (EMC)
Work relevant to Work- Package(s)	Item description	Amount in €	Explanations of the use of resources
WP6	Personnel direct costs	71.388,60	PHD student €55.429,28. Research Supervisor €4.698,01 Lung Analysis €11.261,31
	Subcontracting [if foreseen in Description of Work]		
WP6	Other direct costs	927,39	Travel costs PHD student J.J. Meerburg travelled to Basel on 06-06- 2016 for General assembly iABC
	Consumables [if applicable]		
	Equipment depreciation [if applicable]		depreciation of important equipment (provide detail)
	Hardware/Software/licence costs		
	Indirect costs	14.463,20	e.g. 20% flat rate, actual indirect costs
TOT	AL COSTS	86.779,18	
Budget	for the period		
D	eviation		

### - Reporting of costs incurred by EFPIA companies

TABLE: P	ERSONNEL AND OTHER MAJO	R COST ITEMS INC	CLUDING SUBCONTRACTING
[1-Basilea Pharmac	ceutica 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, amdment of DoW, preparing periodic report for Y1 (WP1), finalisation of feasibility report (WP2),
	<b>Subcontracting</b> [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 final	ncial contribution		
Total in k	ind contribution	73'698.00	
	EU in kind contribution <sup>2</sup>		Please specify the type of costs
Budget for the period		239'481	
D	eviation	-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.

<sup>&</sup>lt;sup>2</sup> when there is a special clause 13 in the Grant Agreement

TABLE: P	ERSONNEL AND OTHER MAJO	R COST ITEMS INC	CLUDING SUBCONTRACTING
Pa	articipant 3; Novartis Pha	rma 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	<ul> <li>9.22 fully loaded FTEs (=110.7 PMs) engaged in:</li> <li>WP1: Novartis representatives in iABC governance (coordination Unit, Management Board and SCOC)</li> <li>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</li> <li>WP6: Co-leader and support to all activities linked to Bronchiectasis Phase-2 study</li> </ul>
WPs: 4B	<b>Subcontracting</b> [if foreseen in Description of Work]	531,143.31	WP4B: Ongoing contracts with 4 vendors on iBEST-1 Phase-2 study
WPs: 4B	<b>Consumables</b> [if foreseen in Description of Work]	0.0	<b>Note:</b> 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
Cub total in	Lind contribution	2 266 000 94	
	kind contribution	2,366,000.84 752,580.38	WP1 & WP6: QUB (Queen's University Belfast)
Total in k	ind contribution	3,118,581.22	
Of which Non-E	U in kind contribution <sup>3</sup>	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
D	eviation	-863,461.78	[Note: WP4B Consumables not yet included]

<sup>&</sup>lt;sup>3</sup> when there is a special clause 13 in the Grant Agreement

# 6 Form C and Summary Financial Report

FINAM		V - FORM C e filled in by each EFPIA company	
Project or	115721	Funding scheme BH Research	Project
Projuct Aaronym	IABC Programme		
Period trem	01/08/2016	ls this an adjustment to a previous statement?	No
le le	a1/07/2017		
Lega Nanie	Beglies Pharmacaulics International AG	Pasticipant locality Code (PIC)	952807610
Organisation short Nanta	Basilas	Farlicieant nor	1
		Judirect Costs	
		With out parallel and actual induced costs?	Yes
		Multical treated on flat rate of 20 % ?	No
Decimation of aligible in Mind on	giribution (in.E)		
			Amour1
aradimid dosta			72,967.98
diom tracking			0.00
inn direct clasts			0.00
diract casts			0.00
Jal			73,967.99
Declaration of Financial contribution	ution		
Did you provide any figancial contri		ertickoent under spectal clause 117	No
		clause 11 to whom you provided a financial	
Please mention the latal amount (i	n 6), # you provided & contributio	on L	00.00
Tols in Kind contribution (1 + 2	1		73,987.59
f which in kind contribution for rese- coordance with special clause 13 a)		o a Member State or an associatod country, in ses applies	0,00
Certificate on the methodology			
Do you declare costs based on a o agreement?	enlified methodology on in kind	contribution according to Art. II. 13.4 of the grant	Yes
Do you declare average parsonnel	costs according to Art. II.13.2 c	i the grant egmentent?	No
	whiled by an independent audit	or and approved by the European Commission	No
Certificate on the financial state	n onis		
there a pertolectio on the linencie's	presentent? (The requirement to pro refere costs on the basis of a cardia	centeral auditor attached to khis Unancial statement who a centerio or the francas statements shalloo is methodoxy or accordence with Art. 13 4 or the grant of costs on the basis of a cartified methodoxy ayarand methodox (at 11 - 6 ) who can an another methodoxy ayarand	No
aved for mose EFFIA companies Stal d	event's Framework Programme in A	defensaries waaried, witht with the constraint affention of accelor	

sigible costs specified in Art. II.13 and II.14 and Article 7 (special douses) of the grant agreement; - there is full supporting documentation to justify the information hereby declared, if will be made available at the request of the tMI JU and in the event of an audit,

EFFIA company's Stamp	Name of the Person(s) Authorised to sign this Financial Statement
	Androas Kümin, Pätrick Goisor
	Date & signature
1	2/03/2017 G. J not show at the

Profest by S0704 on S017-33-32

FINANC	and the second	V - FORM C tilled in by each EFPIA company	
Project nr	115721	Funding scheme MI Resoar	rch Project
Project Acronym	iABC Programme		
Period from To	01/08/2016 31/07/2017	is this an acjustment to a previous statement?	No
Legal Name	Novartis Pharma AG	Participant Identity Code (PIC)	898754567
Organisation short Name	NOV	Participant nbr	3
1-Declaration of eligible <i>in kind</i> col	it/Dution (in ©)	Indirect Costs Nethod based on actual indirect costs? Nethod based on flat role of 20 %?	Yes Na
			Amount
Personnel costs		- Law -	1,834,85
Subcontracting			631,14
Other direct costs Indirect costs			
Total			2,366.00
A REAL PROPERTY AND A REAL		and the second s	ale celes
2- Declaration of Financial contribut		reaction of the state of the state	
Did you provide any financial contrôl If you, please come the beceficiens?		artioloant under special clause 11? clause 11 to whom you provided a financial	Yes QUB (Queen'
anthibution Flease mention the total amount (in			University Belf
3- Total In Kind contribution (1 + 2)			3,118,58
CONTRACTOR CONTRA		e a Member State or an associated country, in sea applies	1,434,34
4- Certificate on the methodology Do you declars costs based on a ce agreement?	rtified methodology on in kind-	contribution according to Art. II. 13.4 of the grant	Yes
Do you declare average personnel :	osts according to Art. II. 13.2 c	f the grant agreement?	No
is there a cartified methodology pro- accarding to Art. 8.13.2 of the grant		ar and approved by the European Commission	No
5-Certificate on the financial states			
eccording to Art. II.4.4 of the grant egr waives for those SPPIA companies that des agreement, and for those SPPIA companies	eernen!? (The requirement to pro- lare costs on the basis of a certifie ; that doclare personnel and institu- renth Framework Programme in ac	endent euditor attached to this financial statement vido a actificate an the theorial statements sheb be d mathaology in eccedence with Art. If 13 4 of the grant d costs on the nask of a certified methodology approve costance with Art. If 12.2, of the grant apreament, except	No
Name of the auditor		Cost of the certificate (in E)	
aligible costs specified in Art. II.13 a - there is full susporting documental the event of an audit.	tly related to the reacurces use no II.14 and Article 7 (special )	ad to attain the objectives of the project and fail within clauses) of the grant sgreement; weby declared, it will be made available at the reque	
EFPIA company's Stamp		erson(s) Authorised to sign this Financial S	
Novartis Pharma AG	Vincent Malaterre, Glob	al Program Team Director: Sebastian Schlechtrie Development Respiratory & E	m, Head Finance
P.O. Box	States in the second second	Date & signature	STATISTICS IN THE
CH-4002 Basel	43/03/2017	Le 25/05/17 /	111 .
		>	

#### IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT ANNEX V - FORM C FINANCIAL STATEMENT - to be filled in by each beneficiary IMI Research Project Project nr 115721 Funding scheme Project Acronym IABC Programme Period from 01/08/2016 No Is this an adjustment to a previous statement? 31/07/2017 То The Queen's University of Belfast Participant Identity Code (PIC) 999992013 Legal Name Organisation short Name QUB Participant number in the project 2 Indirect Costs Funding % for RTD activities (A) 75 % 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 Management Training Other (A) (**B**) (C) (D) 157,460.19 0.00 Personnel costs 183.593.79 0.00 341.053.98 Subcontracting 1,794,934.70 0.00 0.00 0.00 1,794,934.70 Other direct costs 272,624.80 272,624.80 0.00 0.00 0.00 Sub-total direct costs 2,251,153.29 167,460.19 0.00 0.00 2,408,613.48 Indirect costs 122.735.76 0.00 0.00 91.243.72 31.492.04 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? Yes If yes, please mention the amount (in $\epsilon$ ) 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 No according to Art. II 16 of the grant agreement? 0.00 If yes, please mention the amount (in €) 3-Declaration of interest vielded 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? No If yes, please mention the amount (in $\epsilon$ ) 0.00 4-Certificate on the methodology Do you declare average personnel costs according to Art. II 13.2 of the grant agreement? No Is there a certified methodology provided by an independent auditor and approved by the European Commission according to No Art. II 13 2 of the grant agreement? 5- Certificate on the financial statements Is there a certificate on the financial statements provided by an independent auditor attached to this financial statement according to Art. II 4.4 of the grant agreement? (The requirement to provide a certificate on the financial statements shall be waived for those beneficiaries that declare personnel and indirect costs on the basis of a certified methodology approved by the European Commission within the Seventh Framework Programme in accordance with Art. II.13.2 of the grant agreement, except for the final reporting period. Art. II.4.5 of the grant agreement.) Yes 1,275.58 Name of the auditor KPMG Cost of the certificate (in C) 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 the costs 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
	Aveen Lavery
QUEEN'S UNIVERSITY BELFA	Date & signature
	I very 13/10/17
7	V
RESEARCH SUPPORT OFFICE	

FIN	IANCIAL STATE	ANNEX V - FO MENT - to be fi	DRM C lled in by each <i>bene</i> i	ficiary	
Project nr Broject Asronum	1157		Funding scheme	MI Research	Project
Project Acronym	iABC Pro	gramme			
Period from	01/08/2015		Is this an adjustment to a	previous statement?	Adjustment to
Το	31/07/2016		86 - 85 - <b>-</b>	·	period 1
Legal Name	The Queen's Univ	and the second se	Participant Identity		999992013
Organisation short Name	QU	8	Participant number	is the project	2
			Indirect Co	osts	
Funding % for RTD activit	ties (A)		Method based on actual in		No
			Method based on flat rate	of 20 %?	Yes
- Declaration of eligible costs (in £)		Typ	e of Activity		
	RTD	Management	Training	Other	TOTAL
	{A}	(B)	(G)	(D)	(A+B+C+D)
lersonnel costs lubcontracting	0.00 4,717.52	0.00	0.00	0.00	4,717.5
Dither direct costs	-196,213.33	-272.13	0.00	0.00	-196,485.4
Sub-total direct costs	-191,495.81	-272.13	0.00	0.00	-191,767.9
ndirect costs	-39,242.67	-54.43	0.00	0.00	-39,297.1
otal	-230,738.48	-326.56	0.00	0.00	-231,065.0
laximum IMI JU contribution	-173,053.86	-326.56	0.00	0.00	-173,380.4
- Declaration of receipts 2a) Did you receive any financial c If yes, please mention the amount (in		EFPIA company?		E	No
<ul> <li>2- Declaration of receipta</li> <li>2a) Did you receive any financial c If yes, please mention the amount (in 2b) Other receipts Did you receive any financial transfer or from a participant under special cl.     </li> </ul>	) €) rs or contributions in k ause 11, or did the pro	ind, free of charge in		lered a receipt	No
2- Declaration of receipts 2a) Did you receive any financial c If yes, please mention the amount (in 2b) Other receipts Did you receive any financial transfer	e €) rs or contributions in k ause 11, or did the pro reement?	ind, free of charge in		lered a receipt	No 0.0
2- Declaration of receipta 2a) Did you receive any financial c if yes, please mention the amount (in 2b) Other receipts Did you receive any financial transfer or from a participant under special cli according to Art. II.16 of the grant ag if yes, please mention the amount (in	€) rs or contributions in k ause 11, or did the pro reement? n €)	ind, free of charge fr oject generate any in	come which could be consid	lered a receipt	No 0.0
If yes, please mention the amount (in 2b) Other receipts Did you receive any financial transfer or from a participant under special cli according to Art. II.16 of the grant ag	<ul> <li>€)</li> <li>s or contributions in k ause 11, or did the pro reement?</li> <li>€)</li> <li>the pre-financing (on</li> </ul>	ind, free of charge fr oject generate any in ly for the managing e	come which could be consid entity of the IMI JU funding)	lered a receipt	0.00
Declaration of receipta     2a) Did you receive any financial c     If yes, please mention the amount (in     2b) Other receipts     Did you receive any financial transfer     or from a participant under special cli     according to Art. II.16 of the grant ag     If yes, please mention the amount (in     Declaration of Interest yielded by 1	<ul> <li>€)</li> <li>s or contributions in k ause 11, or did the pro- reement?</li> <li>€)</li> <li>the pre-financing (on enerate any interest and</li> </ul>	ind, free of charge fr oject generate any in ly for the managing e	come which could be consid entity of the IMI JU funding)	lered a receip!	No 0.0 No 0.0
2- Declaration of receipta     2a) Did you receive any financial c     If yes, please mention the amount (in     2b) Other receipts     Did you receive any financial transfer     or from a participant under special cl     according to Art. II.16 of the grant ag     If yes, please mention the amount (in     2- Declaration of Interast yielded by I     Did the pre-financing you received gu     If yes, please mention the amount (in	<ul> <li>€)</li> <li>s or contributions in k ause 11, or did the pro- reement?</li> <li>€)</li> <li>the pre-financing (on enerate any interest and</li> </ul>	ind, free of charge fr oject generate any in ly for the managing e	come which could be consid entity of the IMI JU funding)	lered a receipt	No 0.0 No 0.0 No 0.0
A Declaration of receipta     A Did you receive any financial c     If yes, please mention the amount (in     2b) Other receipts     Did you receive any financial transfer     or from a participant under special cl.     according to Art. II.16 of the grant ag     If yes, please mention the amount (in     Declaration of Interest yielded by 1     Did the pre-financing you received ge     If yes, please mention the amount (in     Certificate on the methodology     Do you declare average personnel c	<ul> <li>€)</li> <li>rs or contributions in k ause 11, or did the pro- rement?</li> <li>c)</li> <li>c)</li> <li>d)</li> </ul>	ind, free of charge in oject generate any in ly for the managing e ccording to Art. II 18 II 13 2 of the grant as	come which could be consid entity of the IMI JU funding) of the grant agreement? greement?	E	No 0.0 No 0.0
2- Declaration of receipts     2a) Did you receive any financial c     If yes, please mention the amount (in     2b) Other receipts     Did you receive any financial transfer     or from a participant under special cl     according to Art. II.16 of the grant ag     If yes, please mention the amount (in     2- Declaration of Interest yielded by 1     Did the pre-financing you received ge     if yes, please mention the amount (in     2- Certificate on the methodology	<ul> <li>€)</li> <li>rs or contributions in k ause 11, or did the pro- rement?</li> <li>c)</li> <li>c)</li> <li>d)</li> </ul>	ind, free of charge in oject generate any in ly for the managing e ccording to Art. II 18 II 13 2 of the grant as	come which could be consid entity of the IMI JU funding) of the grant agreement? greement?	E	No 0.0 No 0.0 No 0.0
2- Declaration of receipta     2a) Did you receive any financial c     If yes, please mention the amount (in     2b) Other receipts     Did you receive any financial transfer     or from a participant under special cli     according to Art. II.16 of the grant ag     If yes, please mention the amount (in     3- Declaration of Interest yielded by 1     Did the pre-financing you received ge     If yes, please mention the amount (in     2- Certificate on the methodology     Do you declare average personnel co     Is there a certified methodology provi	<ul> <li>€)</li> <li>rs or contributions in k ause 11, or did the provident?</li> <li>c)</li> <li>c)</li> <li>the pre-financing (on enerate any interest an e)</li> <li>c)</li> <li>osts according to Art.</li> <li>ided by an independe</li> </ul>	ind, free of charge in oject generate any in ly for the managing e ccording to Art. II 18 II 13 2 of the grant as	come which could be consid entity of the IMI JU funding) of the grant agreement? greement?	E	No 0.0 No 0.0 No No
2- Declaration of receipta     2a) Did you receive any financial c     If yes, please mention the amount (in     2b) Other receipts     Did you receive any financial transfer     or from a participant under special cl     according to Art. II.16 of the grant ag     If yes, please mention the amount (in     2- Declaration of Interest yielded by 1     Did the pre-financing you received ge     If yes, please mention the amount (in     2- Declaration of Interest yielded by 1     Did the pre-financing you received ge     If yes, please mention the amount (in     2- Certificate on the methodology     Do you declare average personnel c     Is there a certified methodology prov.     Art. II 13 2 of the grant agreement?	<ul> <li>€)</li> <li>rs or contributions in k ause 11, or did the pro- rement?</li> <li>c)</li> <li>the pre-financing (on enerate any interest an osts according to Art. ided by an independe ents.</li> </ul>	ind, free of charge in oject generate any in- ly for the managing e ccording to Art. II 18 II 13.2 of the grant a nt auditor and approv an independent audit a certificate on the final hodology approved by it	come which could be consid entity of the IMI JU funding) of the grant agreement? greement? ved by the European Commi for attached to this financial s nicial statements shall be waived i he European Commission within t	ission according to statement according for those beneficiaries the Seventh Framework	No 0.0 No 0.0 No No

Name of the Person(s) Authorised to sign this Financial Statement

Aveen Lavery
Date & signature

20

13/10/17

#### IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

Beneficiary's Stamp

QUEEN'S UNIVERSITY BELFAST

RESEARCH SUPPORT OFFICE

### IMIJOINT UNDERTAKING MODEL GRANT ACREEMENT

FIN	ANCIAL STATE	ANNEX V - FO	DRMC illed in by each <i>ben</i> e	fictery	
Plajest hr	1163	24	Funding scheme 🔚	MI Requests	Wojeci.
Propert Annuny n	IADC Pro				
Teriod from To	09008/2016 8909/2017		ta this an acjustment to a	provious slatement? 🦲	No
Lega Norto	University Mindres	Center Usrecht	Part of part fountily	, Cede (P10)	89991.5188
Court sation shows by the	UNK		Parkeisan: number		4
			for rate 21	пках	
Find (375 for 31.1 arrist	<ə (A)	TE %	Method Lasice on action (		Ha
A manufacture of all this same in Fi			Mithial based on flat rate	or 20 \57	Yas
1- Declaration of eligible costs lin C		lyp	e of Amizly		
	6.10	Management	training	Dilter 10'	TOTAL A DICIDI
Parsonne cerde	T7.935.00	10,207,49		0.00	89,182.00
Super traduce	0.00	0.00	00.4	0.09	0,40
Other direct contra	32.497.80	0.66	00.0	0.08	33,497.01
Sub-botal direct costs	111,072.00	10,207.00	00.0	0.04	121.279.00
huaro Daratá	22,244,44	2,041,48	0.00	0.00	24,255.80
Total	122,285,44	12,248.40	0.00	6.08	112,213,20
Nacious INI JU centritetion Requested INI JU contribution	98,964.09	12,000,00		4.40	112,213,00
<ul> <li>20) Other nonliptic</li> <li>20) Other nonliptic and manufacture of the second process of the second proces of the second proces of the second process of the s</li></ul>	vog 77, er ein Malpe anman? El Harava any Infansita (er Harava any Infansita El Mar according fa Art	speer generate any in ity for the managing- scondung to Art. If. (3 X.1.3.2 of the grant a	come which could be considered entity of the IMI JU funding: of the grant equesivent? presencent?		No No No
B: Contigente en the Research Alektons in Analysis activity of the Research and the Second and the Analysis activity of the Analysis activity of the Analysis activity of the Research activity o	ensants download download e opport of a contraction may be a set of a contraction may be a set of a contraction may be a set of a set of a set of a many be a set of a set of a set of a contraction of a set	ex owhitek an U. And trading registion of the registion of the list register (registion of the list register) (registion of the list of the registion of the list of the written of the declar mattern for the declar	nava subtractors 604 de valide la Sungeor d'Openspone anton y generi 44, 4,4,3 of the positie Const of the const Local of the grant agreement subgeories of the grant agreement iscered as receipts according iscered as receipts according (a. Il will be made available)	Compose power-bases (re-second - termine of the powerson ) (care tim C) and foll withen the clehr tim (c) and foll wither the clehr tim (c) and the recruited of the Mid.	free of charge, from agreement; IU and is the event

Bens Strikry's Slamp	Name of the Person(a) Authorized to sign this Financial Statement
	Ferniko Kothelis
	Date & signature
	A A A A A A A A A A A A A A A A A A A
	31/08/2017

w area by SCED, an SOL7 75-26

Project nr Project Acronym	1157 iABC Pro		Funding scheme	(MI Research	Project
Period from	01/08/2016		Is this an adjustment to a	previous statement?	No
То	31/07/2017 Belfast Health a	nd Social Care			99834893
Legal Name Organisation short Name	Tru BHS	st	Participant Identity Participant number i	and the second s	5
organisation energiane			Indirect Co	osts	
Funding % for RTD activit	ties (A)	75 %	Method based on actual in	direct costs?	No Yes
1- Declaration of eligible costs (in €)			Method based on flat rate		163
	RTD (A)	Ty; Management (B)	oe of Activity Training (C)	Other (D)	TOTAL (A+B+C+D
Personnel costs	0.00	0.00	0.00	0.00	
Subcontracting Other direct costs	0.00	0.00	0.00	0.00	
Sub-total direct costs	0.00	0.00	0.00	0.00	and the second second
Indirect costs Total	0.00	0.00	0.00	0.00	
Maximum IMI JU contribution	0.00	0.00	0.00	0.00	YAE/ TOYA
Requested IMI JU contribution	1			Ļ	
		<b>FEDIA</b>		Γ	No
2- Declaration of receipts	antributio- from				
2a) Did you receive any financial o		EFPIA company/		0	
2a) Did you receive any financial o If yes, please mention the amount (in 2b) Other receipts	n €)		in a third partiag	t	
2a) Did you receive any financial o If yes, please mention the amount (in 2b) Other receipts Did you receive any financial transfe or from a participant under special ci	n €) rs or contributions in l ause 11, or did the pr	kind. free of charge (	rom third parties ncome which could be consid	ered a receipt	No
2a) Did you receive any financial o If yes, please mention the amount (in 2b) Other receipts	n €) rs or contributions in l ause 11, or did the pr rreement? n €) <b>the pre-financing</b> (or enerale any interest a	kind, free of charge i oject generate any i nly for the managing	entity of the IMI JU funding)	lered a receipt	No No
<ul> <li>2a) Did you receive any financial of If yes, please mention the amount (if 2b) Other receipts</li> <li>Did you receive any financial transfe or from a participant under special claccording to Art. II. 16 of the grant ag If yes, please mention the amount (if 3- Declaration of interest yielded by Did the pre-financing you received g If yes, please mention the amount (if 4- Certificate on the methodology Do you declare average personnel of Is there a certified methodology prov. Art. II. 13.2 of the grant agreement?</li> <li>5- Certificate on the financial statem Is there a certificate on the financial statem Is the costs declared above are direct specified in Art. II.13 and II.14 of the - the receipts declared above are the the the declare on specified in Art. II.13 and II.14 of the - the receipts declared above are the the state set of the auditor</li> </ul>	n €) rs or contributions in l ause 11, or did the pr rreement? n €) the pre-financing (or enerate any interest a n €) costs according to Art. rided by an independent idements provided by the requirement to provide he basis of a certified me the grant agreement, ex- product thy related to the resou- grant agreement and a only financial contrili-	kind, free of charge i oject generate any i hly for the managing according to Art. II, 18 II, 13.2 of the grant i ent auditor and appri- thadology approved by cept for the final report urces used to attain I Article 7 (special d putions from EFPIA i uwhch cuild be core	ncome which could be consid entity of the IMI JU funding) B of the grant agreement? agreement? sved by the European Commi litor attached to this financial s ancial statements shall be waived the European Commission within ng period: Art. II.4.5 of the grant ag Cost of the certif the objectives of the project a auses) of the grant agreemen companies, financial transfers	ission according to statement according for those beneficiaries the Seventh Framework greement.) iteate (in C) and fall within the definit it; or contributions in kinc to Art. II 5 of the gran	No No No No ion of eligible c
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<ul> <li>2a) Did you receive any financial of if yes, please mention the amount (if 2b) Other receipts</li> <li>Did you receive any financial transfe or from a participant under special cl according to Art. II. 16 of the grant age if yes, please mention the amount (if</li> <li>3- Declaration of interest yielded by:</li> <li>Did the pre-financing you received g if yes, please mention the amount (if</li> <li>3- Declaration of interest yielded by:</li> <li>Did the pre-financing you received g if yes, please mention the amount (if</li> <li>4- Certificate on the methodology</li> <li>Do you declare average personnel of is there a certified methodology prov Art. II. 13.2 of the grant agreement?</li> <li>5- Certificate on the financial statem is there a certificate on the financial statem is there a certificate on the financial statem is there a certificate and indirect casts on i programme in accordance with Art. II. 13.2 of Name of the auditor</li> <li>6- Beneficiary's declaration on its here the receipts declared above are direct specified in Art. II. 3 and II. 14 of the the receipts declared above are direct specified in Art. II. 3 and II. 14 of the the receipts declared above are direct specified in Art. II. 3 and II. 14 of the the receipts declared above are there is full supporting documentat of an audit by the IMI JU and/or, if a authorised representatives.</li> </ul>	n €) rs or contributions in 1 ause 11, or did the pr recement? n €) the pre-financing (or enerate any interest a n €) costs according to Art. rided by an independed ents terments provided by the requirement to provide he basis of a certified me (the grant agreement, ex- propur ty related to the resou- grant agreement and a only financial contril nerated by the projection on to justify the inform pplicable (cfr section r only interest yielded b	kind, free of charge i oject generate any i hly for the managing according to Art. II, 14 II, 13.2 of the grant i ent auditor and appri- ent auditor and appro- ent for the final report urces used to attain a Article 7 (special cl putions from EFPIA of unition hereby decla II.3 of Annex II), by t y the pre-financing w	ncome which could be consid entity of the IMI JU funding) a of the grant agreement? agreement? oved by the European Commi litor attached to this financial s ancial statements shall be waived the European Commission within ag penod: Art. It.4.5 of the grant ag Cost of the certif the objectives of the project a auses) of the grant agreemen companies, financial transfers sidered as receipts according red. It will be made available the Commission (including OL	ission according to statement according for those beneficiaries the Seventh Framework preement). Teate (in C) and fail within the definit it; or contributions in kinc; to Art. II.16 of the gran at the request of the IM AF) and the Court of A	No No No No ion of eligible of d, free of charge t agreement; I JU and in the uditors and/or t at agreement,
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### IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

Printed by SOFIA on 2017-09-21

IMPLICANT.	UNDERTAKING	малы	GRANT	AMERICANENT

Project nr	£16.	721	Funding scheme	In Research	Project
Project Acronym	MDC Pro	gramme ;			
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	Freenhofer-Ge	ealleabolt zur		and the second second	
Legal Name	Förderung der	engewyndten	Participant Identity C	ode (PIC)	995964060
Organization short Name	Fóracha Frauchói		Participant number in	(in control )	Б
Orgenisation anormaine					P
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l'unding % for RTD activ	nivs (70)		Method based on flat rate of		Yes
Declaration of clothin cools (in O			neares assessed on his rate of		110
			of Activity	State States	
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Printee by SD/TA on 2817-05-25

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	IMI JOAN UN	DERTAKING MOD	EL GRANT AGREEMENT		
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Proje se Agror , m	IABC Prog				
Period from	01/00/3015		la tris en adiustment t	a a provious sistement?	Adjutament so excludi 1
In	31/07/2018			L	
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Grganisation stion Name	SERM	89	Pania pertinoma	enin like arajed	8
		73 5	todirret Motioni kasioo ee acius		No
Funding % for RTC assiv		19.2	Method bases on flat ra		Yaa
i- Declargtion of eligible costs (in C		<b>T</b>			
	870	Nara <u>c</u> umuni Naracumuni	no of Activity Training	Cibre	TOTAL
	14	间:	(5)	(0)	(A+3+C+D)
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iubcontrauting	00.0	0,08	1.00	00.0 00 0	
jilinin _ reci Casis	00.0	4.00	0.00	+uu +.00	
Sub-Iolal direct costs	1,065,81	4.00	DAD		1,085.61
mbard rests	219.52	# Q0	000	00.4	210.12
Tera:	1,314,735	0.0.8		040	2,314.73
Assimumi IM JU contribution 🦉 🦉	20.369	00.0	0.00	020	<u>936.05</u> 936.05
Sa) Did you receive any finansia If yas, ploose mention the amoun! ( 2b) Other receipts	(n €)			t	No 
Old you receive why ladvaid intensit or inten with the family and and or social of according to Art. X.16 of the grant a	slause 11, or did the pro	nd, inse ol c'harge i feel generele engli	kom third parties nggmy which cashe balles	nsidares g receip'	No
If yes, please mention the amount (	hanĝ			l	0.04
3-Declaration of Interast visional, by					
Div the pre-linencing you received,		coming to Art. 0.1	в ој ни учин оргаалкит		No
V yea - plaaso maniloo ika amaunt (	19 El				0.01
4- Çeştilî caha na ilva mathodology	es me a se sembra da dad. I				No
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An. //. 13 Z of the grant agreement?				'	
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Non-ten and the succession of	of the termining or prevention of the terminal second	eos for the final report	Cost of Park	erificate (in C)	0.0
0- Canaffolany's declaration on its i	-DROUT				
a conservation in sector status and the first of the doctor of our handware field. - the costs declared above are done specified in Art, 11.3 and 11 h of the - - tip respect indexident doctor and the doctor and the initial parties and the only income p - tip respect by the tith UB anther, 10 and the title of the of an equility by the tith UB anther, 10 and the title of the other of the sector	city restated in the massa a gued a guertoru and re only financial contrib enstated by the orologic tion to justify the inform	Articla 7 (special c Joans Fort Ef PIA which could be con actos homby Secto	lausesi oli ihe graat ayree companisa, iiožoržot trans syldurodi as recetpts accov redi it will bo made ava4ol	ment) firs an common ans in him dang to Ari, II, 16 di the gree big ai (ne perpensi di ini his	d, tree of charge. (mr al agreemént) 1 JU and in the overt
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Most of character Strongs	Name of the Person(s) Authorised to sign this Effancial Statement
	JOSÉ IBNACHI FLORES NEOLÀS
18	Date & signature
FIBio-HRC	24" september, cort
Wennam The	

NUMBER OF SOFIA OF 2017-09-37

	NANCIAL STATE	ANNEX V - FC MENT - to be fi	lied in by each barren	clary	
Project or Project Actornyis	1167: BABC Prog		Foodlog salicant 🔤	Mi Marearch I	Projoci
l'arlod hrom Fu	01/08/2016		is this on adjustment $\mathbf{x}$ a $\boldsymbol{\rho}$	nevioss statement?	No
Légal Naice Organisation short Narro	Universiden Zeihen LIZA		Participani litenniy Participani number in		996727896 9
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<u>Destarațion of alloitile costa /lo.6</u>	،			F2017. F	FUD
	RTD IA)	Vanagemt 17 (14)	e of Activity Training 1C)	эµе-  Dj	TOTAL (A) (D) (D+ 2)
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ihr ant te fing - ur direct costa	0,00	0.10	0.65	0.00	1,0#
b total direct costs	47.012.47	38,493,64	0,04	0.00	17,493.17
ilirect coata	9,662.49	7,938.71	0.00	0.00	17,499.30
ul .	\$7,374.95	47,620.26	d.04	0.00	104,996.21
numum (M)	43,034.22	47,520.25	0.M	0.00	99,591,47 99,591,47
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relative a ment of the station of the	and any interest of	containing for Arts, (1, 1, 0, o	d the grant agreement?	1	Ri e
Did the pre-financing you received ( Kiyes, please menden the amount (		-		Ľ	00.0
Did the pre-financing you received (	ln € nasts accarding is Aur JJ Matericy an intercenter	73 2 of the grant ag t author and spore	veament? da'by Me Eincbesh Camma	aios accorolog lo	
Did the pre-financing your received ( Kryes, places mendion the amount ( Cortificate on the methodiology Do you declare as arage personnel is frame a perified methodiology co	In Sj maska accurating to Aur. JJ refereing an independen nemin (whereas) proceeds by a j	f auchor and spores	dal by she Eindursh Gamma Ir allachea la fills fitentiel en Gamma searchea	Element poponing Intra-Londonner e Sana di Pangarati Billion.	0.00 No
District the pre-friencing you monited if yes, phone mention the answer ( <u>Confidence on the motionicles</u> ) to you derive a usage persamet for there a consider a minocality pro- duit $h$ (3.2 of the gravit equivariant there a confidence on the financial states that a confidence of the financial states that a confidence of the financial states confidence of the financial that a confidence of the financial that a confidence of the financial states confidence on the financial is setting confidence on the financial is setting confidence on the financial states confidence on the financial states is setting confidence on the financial states of the set is setting confidence on the financial states of the set is setting confidence on the financial states of the set is setting confidence on the set is set in the set is setting confidence on the set is set in the set is set in the setting confidence on the set is set in the set is set in the setting confidence on the set is set in the set is set in the setting confidence on the set is set in the set in the set is set in the setting confidence on the set is set in the set is set in the set is set in the set in the set in the set in the set is set in the set in the set in the set is set in the set in th	In Eg casts accurding to Arr JJ victod by an indecendent internal internal internal provided by ar- internal internal constant of provider internal internal internal constant of provider internal interna	r independent and approve a independent aus/it is performed to the stars about the instruments is a the time remotes is a the time remotes is a time to the stars internet is a star the stars is a star is a time terms in the stars is a time to the stars is a t	ad by 46 Eincytest Carman or staathao to fitta forantsei an cal antitetta shat for straatt Strapper Consideration attact at a 2001 e geringe to statistic contille s objectives of the project an social of the generation social of the generation specta a receipts according to a Commission (Including OLA	Maniett ródyomány i tran Astvoltavier i Senakti Paregingta stratsu statu (In C) d Isil within the definition in echelikustenia kind.) o An. II. 16 of the grant the request of the INI JI P and the Court of Aug	No No No No D.00 n of Sigiple case less of charge, from Symmetric, U and in the expert Hors and/or their
We he pre-financing your received yes, places mention the annound ( initial place an the enclosed place) in your declines as seque personnol there a personal methodology (d, h, f3.2 of the grand agreement? initial place on the financial states and a sent/serie on the financial states and h of the grand agreement? initial case of the grand agreement in the here of the second board of the grand person of the second board of the grand initial case of the opportunity have one due there is full to provide the outer in the here is full to provide documents here is full to provide documents withous and the defined documents withous agreed to presental the defined of the grand Mark POR THE MANG NG EVIT	In Eg casts according to Apr. J. Added by an indecendent accord Mathemanis provided by an Net processor (provide) With plats converse ego With plats converse ego with plats converse or part is greatment and J and plats of the plats of the plats of the plats applicable (of section ill) V	f auchor and approx in nonconstant auch is explored in the Asian story approximation of the all to flue time remotes in the time remotes provide the story of the provide the story of the provide the story of the story approximation of the all of Annox III, by the dia pro-financing wh	ad by 40 Eincodest Carmas or stabilize to fits forances an exception Considered which o parameters and to extreme exception Considered which o parameters and the proposition state of the proposition state of the proposition state of the proposition region of the product state over due to coloris according to a within the calculation o	Winnerty potoming in the standbarren is Senath Paragraph Product Paragraph Product Paragraph d tail within the definition recentration and in Million o Art. III.16 of the grant in Promoti the Court of Aus Promoti the Court of Aus d Art. III.16 of the grant in	No No No No No D.00 D.00 D.00 D.00 D.00 D.00 D.00 D.0
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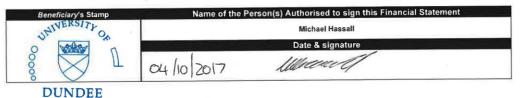
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IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

FIN	ANCIAL STATE	ANNEX V - FO	illed in by each benef	iciary	
				IMI Research I	Project
Project nr	11572		Funding scheme	IMI Research I	roject
Project Acronym	iABC Progr	ramme			
Period from	01/08/2016		Is this an adjustment to a	previous statement?	No
То	31/07/2017				
Legal Name	University of	Dundee	Participant Identity	Code (PIC)	999975523
Organisation short Name	UNIVD		Participant number i	n the project	10
		1	Indirect Co	ete	
Funding % for RTD activit	ties (A)	75 %	Method based on actual in		No
			Method based on flat rate of		Yes
1- Declaration of eligible costs (in €)					
	979		e of Activity Training	Other	TOTAL
	RTD (A)	Management (B)	(C)	(D)	(A+B+C+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	372,677.8
Indirect costs	44,906.78	99.41	0.00	0.00	45,006.1
Total	417,087.54	596.46	0.00	0.00	417,684.0
Maximum IMI JU contribution	312,816.66	596.46	0.00	0.00	313,412.1
2a) Did you receive any financial c		FPIA company?	`	H	No 0.0
		FPIA company?	`		
If yes, please mention the amount (in					
2b) Other receipts Did you receive any financial transfer or from a participant under special cl	ause 11, or did the proj	nd, free of charge f ject generate any i	rom third parties ncome which could be conside	ered a receipt	No
according to Art. II.16 of the grant ag If yes, please mention the amount (ir				F	0.0
				-	
3- Declaration of interest yielded by t	the pre-financing (only	y for the managing	entity of the IMI JU funding)	_	
Did the pre-financing you received g	enerate any interest ac	cording to Art. II.18	of the grant agreement?	-	No
If yes, please mention the amount (in	1 €)			L	0.0
				_	-
4- Certificate on the methodology		1122 of the grant :	greement?		No
4- Certificate on the methodology Do you declare average personnel c	osts according to Art. I	1.13.2 Of the grain a			110
	osts according to Art. I ided by an independen	at auditor and appro	oved by the European Commi	ssion according to	No
Do you declare average personnel c Is there a certified methodology prov Art. II.13.2 of the grant agreement?	ided by an independen	at auditor and appro	ved by the European Commi	ssion according to	
Do you declare average personnel c Is there a certified methodology prov Art. II.13.2 of the grant agreement? 5- Certificate on the financial statem Is there a certificate on the financial state to Art. II.4.4 of the grant agreement? (I	ided by an independen ents itements provided by a he requirement to provide i he basis of a certified meth	it auditor and appro n independent aud a certificate on the fin	wed by the European Commi itor attached to this financial s ancial statements shall be waived I the European Commission within I	tatement according for those beneficiaries he Seventh Framework	
Do you declare average personnel c Is there a certified methodology prov Art. II.13.2 of the grant agreement? 5- Certificate on the financial statem Is there a certificate on the financial state to Art. II.4.4 of the grant agreement? (Ti that declare personnel and indirect costs on II Programme in accordance with Art. II.3.2 of	ided by an independen ents itements provided by a he requirement to provide i he basis of a certified meth	n independent aud a certificate on the fin adology approved by apt for the final reporti	wed by the European Commi itor attached to this financial s ancial statements shall be waived I the European Commission within I	tatement according for those beneficiaries he Seventh Framework reement.)	No
Do you declare average personnel c Is there a certified methodology prov Art. II.13.2 of the grant agreement? 5- Certificate on the financial statem Is there a certificate on the financial state to Art. II.4.4 of the grant agreement? (I	ents ents Itements provided by a he requirement to provide he basis of a certified meth the grant agreement, exce	n independent aud a certificate on the fin adology approved by apt for the final reporti	wed by the European Commi itor attached to this financial s ancial statements shall be waived the European Commission within t g period, Ar. II.4.5 of the grant ag	tatement according for those beneficiaries he Seventh Framework reement.)	No Yes
Do you declare average personnel c Is there a certified methodology prov Art. II.13.2 of the grant agreement? 5- Certificate on the financial statem Is there a certificate on the financial state to Art. II.4.4 of the grant agreement? (Ti that declare personnel and indirect costs on II Programme in accordance with Art. II.3.2 of	ents ents Itements provided by ai he pagurement to provide he basis of a certified meth the grant agreement, exce Henderson	n independent aud a certificate on the fin adology approved by apt for the final reporti	wed by the European Commi itor attached to this financial s ancial statements shall be waived the European Commission within t g period, Ar. II.4.5 of the grant ag	tatement according for those beneficiaries he Seventh Framework reement.)	No Yes

- 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 jusify the information hereby declared. It will be made available at the request of 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.

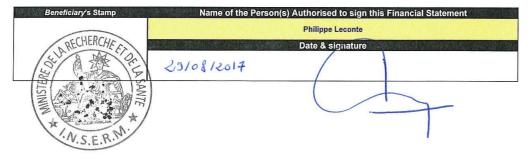


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#### IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

FI	NANCIAL STATE	ANNEX V - FO MENT - to be fi	DRM C lled in by each <i>bene</i>	ficiary	
Project nr	1157	21	Funding scheme	IMI Research	Project
Project Acronym	iABC Prog	ramme			
Period from To	01/08/2016 31/07/2017		Is this an adjustment to a	previous statement?	No
Legal Name	Institut National de Recherche I		Participant Identity	/ Code (PIC)	999997833
Organisation short Name	INSEF	RM	Participant number	in the project	11
			Indirect Co	osts	
Funding % for RTD activ	ities (A)	75 %	Method based on actual in		No
			Method based on flat rate	of 20 %?	Yes
<u>1- Declaration of eligible costs (in €)</u>		Type	e of Activity		
	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 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		-			N-
2a) Did you receive any financial of If yes, please mention the amount (in		FPIA company?		-	No 0.00
2b) Other receipts	10)			L	0.00
Did you receive any financial transfe or from a participant under special ci according to Art. II. 16 of the grant ag If yes, please mention the amount (ir	ause 11, or did the proje reement?			ered a receipt	No 0.00
	•				
3- Declaration of interest yielded by t					N.
Did the pre-financing you received ge If yes, please mention the amount (in		oraing to Art. 11.18 c	t the grant agreement?	-	No 0.00
n yes, please mention the amount (in					0.00
4- Certificate on the methodology					
Do you declare average personnel co					No
Is there a certified methodology prov Art. II.13.2 of the grant agreement?	ided by an independent	auditor and approve	ed by the European Commis	sion according to	No
5- Certificate on the financial stateme	ents				
Is there a certificate on the financial stat to Art. II.4.4 of the grant agreement? (Th that declare personnel and indirect costs on th Programme in accordance with Art. II.13.2. of	he requirement to provide a be basis of a certified methor	certificate on the finance dology approved by the	ial statements shall be waived fo European Commission within th	r those beneficiaries e Seventh Framework	No
Name of the auditor	Sector States and States		Cost of the certific	cate (in €)	0.00
6- Beneficiary's declaration on its ho We declare on our honour that: - the costs declared above are directl acceled in Att 14.2 and 14.4 of the			objectives of the project and	d fall within the definition	n of eligible costs

the costs declared above are directly feated 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.18 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.



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DOLONT UND SCIAKING M	SOOFL GRANT AGREEMENT
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Only applies Not to be filled in by 2 th	FINANCIAL STATE	e 4 "Third part	liled in by <i>third por</i> ies linked to a <i>parti</i> v	cipant" is used	bries
A CONTRACTOR OF A	<u>11572:</u> iAEC ?regmin		ĨĨſſġĸĊŦſĔŢŗĊĻ	ini Research Pro	iject .
	01/08/2016 21/07/2017	la ihis an adju	sztort le a pievi vi élérare	men:7	No
an an hear an ing the state of the second	Université de F: UP		o kung ng sing bila kasi ka		
2 Martin & Starting & Low Forth Starting		-75 V.	ปี 2014 ที่เกิดการเราะระดง ลา นิสามัย (การเมาะวิวาทีกระ) ลา โรงเกิดการเราะระดง(การเ		No Yaa
1-Declaration of <u>allatitic s</u> osts (in €	N RTF 1	CAN CHARDE OF	azalnin v		
Fernantial (2015) Souther Jury States	C.06	<u>620133754768652477586</u> 3.00 3.00	0.09	U.00 C.00 C.00	00.0 00.0 00.0 00.0
Other durent costs different die state of the state of th	<u>0.00</u> <u>0.00</u> <u>0.00</u>	0.00 0.00 	0.00	c.aa	<u>c.au</u>
Masterium (MI JU contribution Requested (Masterium)(Indian	6.63	3.00 9.00	0.00	<u>c.00</u>	<u>c.50 :</u> c.50 : c.60
<ul> <li>22 Declaration of receivits</li> <li>24 Declaration of receivits</li> <li>24 you want to any orient at function y function which could be constructly yes, press mention of 4 40000° (</li> <li>24 Certificates on the methodology of a function of the second second based on the second sec</li></ul>	ed a recard boowwity far n Q cosis according to Art. II, N wasil by an independent a	An UnSoffie gen 22 til ne gen 1 690	Cuttor:2	 	Nu 0.00
Certificate on the financial statem to there a perturbative on the football accessing to April 2 and a difficulty areas the factor football as beneficity if any statement with the Sector and a second and USE of the statement statement football and a statement.	siatemonis providen hy e giazowici? (The sequence) philipitation per anne annual Prenewski Strawn ne o e	'na posyba o antronale Meri costo on 'na baso nandunan mile dia di G	an De navazio' Sistematica) Ofe agraded antica di Sate da Sate da gradi egreciada (c. 6	novite contractions of the second s	NC (.00
Annexistationalized with extra structure We dealer on our forcur that - We dealer on our forcur that - We dealer on our forcur that - We dealer on our force in the specifice in Art. 113 and 0.14 and - We a specificity of the data structure - there is full supplying decaracture of an audit by the ULUL is not in the author sed representatives.	agour (), weiter i binne rasource: victer ((), weiter dataset ( e on yn ner bei feitiwer we (on to tustiv the internation (on to tustiv the internation	s used to other ithe of the grant agreems of and their crisins for gity Ary ithe of the otherwise destates	Ageologic of the project an initia d, the of prange, the movie that provement. I will be motion available of	id fail womin the details. Id carries and the only in The request of the XML.	u pi ejoliko obas rezone generalek Digno pi jago sver L
frigger and diffusions we we	ander ander Reiner Gewöhntensteren		LINE SEALS AND		nexa para di I
	<u>31/8/21/1 14</u>	directeu gó		<u></u>	
Storad by 2014 or 2017-11-24		<u>-2016</u> :			

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	IMI JOINT U	NDERTAKING MO	DEL GRANT AGREEMENT		
F	INANCIAL STATE	ANNEX V - F	ORMC		
	INANOIAL STATE	WENT - to be	filled in by each bene	eficiary	
Project nr	1157	21	Funding scheme		
Project Acronym	iABC Pro	gramme	r unding scheme	IMI Research	Project
Period from	01/08/2016				
To	31/07/2017		Is this an adjustment to a	a previous statement?	No
Legal Name	Università degli s	Studi di Milano	Participant Identit	v Code (BIC)	
Organisation short Name	UMI		Participant number	in the project	999995796 12
					12
Funding % for RTD activ	vities (A)	75 %	Indirect Co	osts	1
1. Deplemention of the sec			Method based on actual in Method based on flat rate	idirect costs?	No
1- Declaration of eligible costs (in €	1		and a subcu on hat rate	0120 % ?	Yes
	RTD	Тур	e of Activity	A CONTRACTOR OF THE	
	(A)	Management (B)	Training	Other	TOTAL
Personnel costs	16,617.50	5,901,14	(C) 0.00	(D)	(A+B+C+D)
Subcontracting	0.00	0.00	0.00	0.00	22,518.6
Other direct costs	0.00	0.00	0.00	0.00	0.0
Sub-total direct costs Indirect costs	16,617.50	5,901,14	0.00	0.00	0.0
Total	3,323.50	1,180.23	0.00	0.00	22,518.64
Maximum IMI JU contribution	19,941.00	7,081.37	0.00	0.00	4,503.73
Requested IMI JU contribution	14,955.75	7,081.37	0.00	0.00	27,022.37
<ul> <li>2a) Did you receive any financial of If yes, please mention the amount (in: 2b) Other receipts</li> <li>Did you receive any financial transfer or from a participant under special cleaccording to Art. II. 16 of the grant agg If yes, please mention the amount (in:</li> <li>Declaration of interest yielded by t</li> <li>Did the pre-financing you received ge If yes, please mention the amount (in:</li> <li>Certificate on the methodology</li> <li>Do you declare average personnel co Is there a certified methodology provid Art. II. 3.2 of the grant agreement? (The at declare personnel and infancial statement in the accound and there a certificate on the financial statement at declare personnel and not ext constrained to the transfer of the grant agreement? (The at declare personnel and not ext constrained to the transfer of the transf</li></ul>	<ul> <li>€)</li> <li>s or contributions in kinause 11, or did the projereement?</li> <li>€)</li> <li>he pre-financing (only inerate any interest according to Art. II.1</li> <li>ted by an independent at the provided by an independent at the presents provided by an in requirement to provide a control of the provide a control</li></ul>	1, free of charge fro ct generate any inc for the managing er ording to Art. II. 18 o 3.2 of the grant agr uditor and approve independent auditor	orme which could be conside http: f the grant agreement? eement? d by the European Commiss attached to this financial stat at statements cool box	ion according to	No 0.00 No 0.00 No No No No
ogramme in accordance with Art. II.13.2. of the auditor	e grant agreement, except	for the final reporting p	eriod; Art. II.4.5 of the grant agree Cost of the certifica	Seventh Framework	0.00
- Beneficiary's declaration on its hom Ve declare on our honour that: - the costs declared above are directly specified in Art. II.13 and II.14 of the gr - the receipts declared above are the o third parties and the only income gene - there is full supporting documentation of an audit by the IMI JU and/or, if appl authorised representatives. ONLY FOR THE MANGING ENTITY	related to the resources ant agreement and Artion nly financial contribution rated by the project which	is from EFPIA comp th could be conside	objectives of the project and as) of the grant agreement, panies, financial transfers or red as receipts according to	fall within the definition of contributions in kind, fre	of eligible costs e of charge, from

L

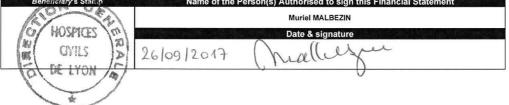
ONLY FOR THE MANGING ENTITY - the interest declared above is the only interest yielded by the pre-financing which falls within the definition of Art. II.18 of the grant agreement. Name of the Person(s) Authorised to sign this Financial Statement ficiary's Stamp TUDIORUA Gianluca Gaetano Vago Gianluca Gaetano Ving Date & signature IL REVIORE Gianjuca Vago 2 8 AGO. 2017 .... Printed by SOFIA on 2017-08-28

Only applica Not to be filled in by a th	FINANCIAL STAT	se 4 "Third parti	illed in by <i>third p</i> es linked to a pa	articipant" is used	iciaries
Project nr	115721	Fun	ding scheme	IMI Research P	roject
Project Acronym	iABC Program	nme			
Period from To	01/08/2016 31/07/2017	Is this an adju	stment to a previous s	statement?	No
Third party legal Name	FONDAZIONE IRCCS OSPEDALE MAG POLICLINIC	GIORE			
3rd party Organisation short Name	IRCCS CA' GR	ANDA We	orking for and linked	to beneficiary nr	12
			Indirect C	osts	
Funding % for RTD activi	ties (A)	75 % Metho	d based on actual indi	AND	No
		Metho	od based on flat rate of	20 %?	Yes
1- Declaration of eligible costs (in €)					
		Type of A	ctivity		
		anagement	Training	Other	TOTAL
Personnel costs	(A) 0.00	(B) 0.00	(C)	(D)	(A+B+C+D)
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
ndirect 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 transfe	rs or contributions in kind	free of charge from	hird parties or did the	project generate	
any income which could be consider				project generate	No
If yes, please mention the amount (in	n €)				0.00
- Certificate on the methodology					
Do you declare average personnel c	osts according to Art. II.1	3.2 of the grant agree	ment?		No
Is there a certified methodology prov	ided by an independent a			nmission according	No
to Art. II.13.2 of the grant agreement	?				110
- Certificate on the financial statem	ents				
Is there a certificate on the financial a according to Art.II.4.4 of the grant ag those third parties linked to a beneficiary th	reement? (The requirement nat declare personnel and ind Framework Programme in ad	to provide a certificate of lirect costs on the basis of	n the financial statement	ts shall be waived for v approved by the	No
European Commission within the Seventh			Cost of the certif	ficate (in €)	0.00
European Commission within the Seventh reporting period; Art. II.4.5 of the grant agr Name of the auditor					
European Commission within the Seventh reporting period; Art. II.4.5 of the grant agr					

dr Simona Giroldi	
2 1000 2017 IL DIRETTORE SENERALE	
Dott.ssa Sijona Giroldi)	

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FIN	NANCIAL STATE	ANNEX V - F MENT - to be	ORM C filled in by each <i>benefi</i>	iciary	
Project nr	11572	21	Funding scheme	IMI Research	Project
Project Acronym	iABC Prog	ramme			•
Period from	01/08/2016		Is this an adjustment to a p	previous statement?	No
То	31/07/2017				
Legal Name	Hospices Civils d General Ho		Participant Identity	Code (PIC)	999469765
Organisation short Name	HCL		Participant number in	n the project	13
			Indirect Cos	ats	
Funding % for RTD activi	ties (A)	75 %	Method based on actual ind		No
1. Declaration of eligible costs (in f)			Method based on flat rate o	f 20 %?	Yes
1- Declaration of eligible costs (in €)	Real States	Ту	be of Activity		
	RTD (A)	Management (B)	Training (C)	Other (D)	TOTAL (A+B+C+D)
Personnel costs	0.00	(B) 0.00	0.00	0.00	(A+B+C+D) 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 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				L	0.00
If yes, please mention the amount (in	E)			Ē	No 0.00
If yes, please mention the amount (in 2b) Other receipts Did you receive any financial transfer or from a participant under special cit according to Art. II.16 of the grant ag If yes, please mention the amount (in	rs or contributions in kin ause 11, or did the proj reement?			red a receipt	
2b) Other receipts Did you receive any financial transfer or from a participant under special ck according to Art. II.16 of the grant ag If yes, please mention the amount (in	s or contributions in kir, ause 11, or did the proj reement? €)	ect generate any i	come which could be consider	red a receipt	0.00 No
2b) Other receipts Did you receive any financial transfer or from a participant under special ck according to Art. II.16 of the grant ag If yes, please mention the amount (in	s or contributions in kin ause 11, or did the proje reement? €) <u>he pre-financing</u> (only	ect generate any in	ncome which could be consider entity of the IMI JU funding)	red a receipt	0.00 No
2b) Other receipts Did you receive any financial transfer or from a participant under special ck according to Art. II.16 of the grant ag If yes, please mention the amount (in 3- Declaration of interest yielded by t	is or contributions in kir, ause 11, or did the proj reement? €) <b>he pre-financing</b> (only enerate any interest acc	ect generate any in	ncome which could be consider entity of the IMI JU funding)	red a receipt	0.00 No 0.00
2b) Other receipts Did you receive any financial transfer or from a participant under special oil according to Art. II. 16 of the grant ag If yes, please mention the amount (in 3- Declaration of interest yielded by t Did the pre-financing you received ge If yes, please mention the amount (in	is or contributions in kir, ause 11, or did the proj reement? €) <b>he pre-financing</b> (only enerate any interest acc	ect generate any in	ncome which could be consider entity of the IMI JU funding)	red a receipt	0.00 No 0.00
<ul> <li>2b) Other receipts</li> <li>Did you receive any financial transfer or from a participant under special cli according to Art. II. 16 of the grant ag If yes, please mention the amount (in</li> <li>2- Declaration of interest yielded by the Did the pre-financing you received ge If yes, please mention the amount (in</li> <li>4- Certificate on the methodology Do you declare average personnel co</li> </ul>	is or contributions in kir ause 11, or did the proje reement? €) <u>he pre-financing</u> (only enerate any interest acc €) osts according to Art. II.	oct generate any in for the managing cording to Art. II.16 13.2 of the grant a	acome which could be consider entity of the IMI JU funding) of the grant agreement? greement?	E	0.00 No 0.00
<ul> <li>2b) Other receipts</li> <li>Did you receive any financial transfer or from a participant under special cli according to Art. II. 16 of the grant ag if yes, please mention the amount (in</li> <li>3- Declaration of interest yielded by t</li> <li>Did the pre-financing you received ge if yes, please mention the amount (in</li> <li>4- Certificate on the methodology</li> <li>Do you declare average personnel cci is there a certified methodology provi</li> </ul>	is or contributions in kir ause 11, or did the proje reement? €) <u>he pre-financing</u> (only enerate any interest acc €) osts according to Art. II.	oct generate any in for the managing cording to Art. II.16 13.2 of the grant a	acome which could be consider entity of the IMI JU funding) of the grant agreement? greement?	E	0.00 No No 0.00
<ul> <li>2b) Other receipts</li> <li>Did you receive any financial transfer or from a participant under special cli according to Art. II. 18 of the grant ag If yes, please mention the amount (in</li> <li>3- Declaration of interest yielded by t</li> <li>Did the pre-financing you received ge If yes, please mention the amount (in</li> <li>4- Certificate on the methodology</li> <li>Do you declare average personnel oc Is there a certified methodology provi Art. II. 13.2 of the grant agreement?</li> </ul>	rs or contributions in kir ause 11, or did the proje reement? €) he pre-financing (only enerate any interest acc €) osts according to Art. II. ded by an independent	oct generate any in for the managing cording to Art. II.16 13.2 of the grant a	acome which could be consider entity of the IMI JU funding) of the grant agreement? greement?	E	0.00 No 0.00 No No
<ul> <li>2b) Other receipts</li> <li>Did you receive any financial transfer or from a participant under special cl according to Art. II.16 of the grant ag if yes, please mention the amount (in</li> <li>3- Declaration of interest yielded by t</li> <li>Did the pre-financing you received ge if yes, please mention the amount (in</li> <li>4- Certificate on the methodology</li> <li>Do you declare average personnel cc is there a certified methodology provi Art. II.3.2 of the grant agreement?</li> <li>5- Certificate on the financial statements is there a certificate on the financial state to Art. II.4.4 of the grant agreement?</li> </ul>	rs or contributions in kir, ause 11, or did the proj- reement? €) he pre-financing (only enerate any interest acc €) osts according to Art. II. ded by an independent ents terments provided by an le requirement to provide a basis of a centified metho	ect generate any in for the managing cording to Art. II.18 13.2 of the grant a auditor and appro- independent audi certificate on the fing dology approved by (	acome which could be consider entity of the IMI JU funding) of the grant agreement? greement? ved by the European Commiss for attached to this financial sta ncial statements shall be waived for European Commission within the	sion according to	0.00 No 0.00 No No
<ul> <li>2b) Other receipts</li> <li>Did you receive any financial transfer or from a participant under special cli according to Art. II. 16 of the grant ag If yes, please mention the amount (in</li> <li>3- Declaration of interest yielded by t</li> <li>Did the pre-financing you received ge If yes, please mention the amount (in</li> <li>4- Certificate on the methodology</li> <li>Do you declare average personnel co Is there a certified methodology provi Art. II. 13.2 of the grant agreement?</li> <li>5- Certificate on the financial statement Is there a certificate on the financial statement Is there a certificate on the financial statement to Art. II. 4.4 of the grant agreement? (Th that declare personnel and indirect costs on the Programme in accordance with Art. II. 3.2. of</li> </ul>	rs or contributions in kir, ause 11, or did the proj- reement? €) he pre-financing (only enerate any interest acc €) osts according to Art. II. ded by an independent ents terments provided by an le requirement to provide a basis of a centified metho	ect generate any in for the managing cording to Art. II.18 13.2 of the grant a auditor and appro- independent audi certificate on the fing dology approved by (	acome which could be consider entity of the IMI JU funding) of the grant agreement? greement? ved by the European Commiss for attached to this financial sta ncial statements shall be waived for he European Commission within the period; Art. I.4.5 of the grant agre	sion according to	0.00 No 0.00 No No No
<ul> <li>2b) Other receipts</li> <li>Did you receive any financial transfer or from a participant under special cli according to Art. II. 16 of the grant agi If yes, please mention the amount (in</li> <li>3- Declaration of interest yielded by the Did the pre-financing you received get If yes, please mention the amount (in</li> <li>4- Certificate on the methodology</li> <li>Do you declare average personnel condition of the grant agreement?</li> <li>There a certified methodology provident and the grant agreement?</li> <li>5- Certificate on the financial statements</li> <li>Is there a certificate on the financial statements</li> <li>Is there a certificate on the financial statement?</li> <li>The declare personnel and indirect costs on the Programme in accordance with Art. II.13.2. of Name of the auditor</li> <li>6- Beneficiary's declaration on its how</li> </ul>	is or contributions in kir ause 11, or did the proje- reement? €) he pre-financing (only enerate any interest acc €) osts according to Art. II. ded by an independent terments provided by an te requirement to provide a e basis of a certified metho the grant agreement, except nour	ect generate any in for the managing cording to Art. II. 16 13.2 of the grant at a auditor and appro- independent audi certificate on the fina dology approved by by at for the final reportin	acome which could be consider entity of the IMI JU funding) of the grant agreement? greement? ved by the European Commiss for attached to this financial sta ncial statements shall be waived for he European Commission within the g period; Art. II.4.5 of the grant agre Cost of the certific	sion according to terment according those beneficiaries Seventh Framework ement.) ate (in €)	0.00 No 0.00 No No No No 0.00
<ul> <li>2b) Other receipts</li> <li>Did you receive any financial transfer or from a participant under special cl according to Art. II. 16 of the grant ag If yes, please mention the amount (in</li> <li>3- Declaration of interest yielded by t</li> <li>Did the pre-financing you received ge If yes, please mention the amount (in</li> <li>4- Certificate on the methodology Do you declare average personnel cc Is there a certified methodology provi Art. II. 13.2 of the grant agreement?</li> <li>5- Certificate on the financial statements Is there a certificate on the financial statements Is there a certificate on the financial statement</li> <li>11.4.4 of the grant agreement? (in that declare personnel and indirect costs on this</li> </ul>	ss or contributions in kir ause 11, or did the proje- reement? €) he pre-financing (only enerate any interest acc €) bits according to Art. II. ded by an independent ents terments provided by an independent oprovide a e basis of a certified metho the grant agreement, excep nour nour y related to the resource grant agreement and A only financial contribut erated by the project w nto justify the informal	ect generate any in for the managing cording to Art. II. 18 13.2 of the grant at a auditor and appro- independent audi certificate on the fina dology approved by ot for the final reportin tor the final reportin es used to attain t tricle 7 (special da ons from EFPIA c hich could be cons ion hereby declar	acome which could be consider entity of the IMI JU funding) of the grant agreement? greement? ved by the European Commiss for attached to this financial sta ncial statements shall be waived for the European Commission within the g period; Art. II.4.5 of the grant agre <b>Cost of the certific</b> the objectives of the project and uses) of the grant agreement; ompanies, financial transfers on idered as receipts according to d. It will be made available at 1	sion according to terment according those beneficiaries Seventh Framework ement) ate (in C) I fall within the definition r contributions in kind, Art. II.16 of the IMJ	0.00 No 0.00 No No No No 0.00 No No 0.00 Un of eligible costs free of charge, from agreement; UJ and in the event



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IM-JOINT JINDERTAKING MODEL GRANT AGREEMENT

FIN		ANNEX V - F	ORM C filled in by each bene	eficiary	
Project ar Project Acronym	136; ABC Pro		Funding scheme	WI Recent	Project
Period from To	01.468/2018 .11.667/2017		la trisian suljua mart tu z	а Биалатк ардаліаціз [	Nu
Legal Name Organisation short Name	MÉDIZINISCHE Hardin Nih	WER	Participant Identit Participant number		880416426
Funding % for FTD activit		76 %	Indirect G Method based on actual in Method based on flai rais	ndirect costs?	No Yeż
	RTD (A)	Tyr Management (B)	er of Activity Training (Cl	Other (D)	TOTAL (A+B+C+D)
Farechicl costs : Subcontracting Other Jirect costs	50,020,0 00.0 , 00.0	0.00 0.00 0.00	6,00 0.01 0.03	0.04 0,04 0.44	4,590.52 4.00 0.00
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(Івовічсмірта Утаптр	Name	of the Personis	Authorised to sign thi	s Sinancial Statemer	nt
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Dritmille absilung Carl Naturg Ginßelf \* 35625 Hannover

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IN JUNT UNDERTAKING MODEL GRANT AGREEMENT

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IMI JOINT UNDERTAKING MODEL GRANT AGREEMENT

	INANCIAL STATE	ANNEX V - F MENT - to be	ORM C filled in by each benef	ficiary	
Project nr Project Acromym	1157 IABC Proj		Fund ng scheme	MI Kesearch	Project
Period from To	01/08/2016 31/07/2017		is this an adjustment to a	previous statement?	No
Legal Name	Royal Brompton & Foundatio	n Trust	Participant identity	Second and the second second	989686507
Organisation short Name	RDH	IT.	Participant number i	in the project	17
Funding % for RTD acti	vities (A)	76 %	Indirect Co Method based on actual in	direct casts?	No
1- Declaration of eligible costs fin 4	a		Method based on Hal rate (	of 20 %?	Yes
	BERGER BURGER		pe of Activity	Vices Di B	
	RTD (A)	Nanagement (D)	Training (0)	Other (D)	(A+B+C+D)
Personnel costs	28,674,68	0.00	0,00	00,3	23,374.
Subcontracting	0.00	00.0	00.0	00.0	0.
Other direct posts	1,584.64	0.00	0.00	00.0	1,594.
Sub-total direct costs	30,469,33	00,0	00,0	0,00	20,469,
Indirect costs	8,093.86	00.0	0.00	0.00	6,093.
Total	36,663.18	00.0	0.00	0,00	16,663.
Naximum INI JU contribution Requested INI JU contribution	27,422.36	00.0	00.9	0.00	27,422 27,422
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MIJOINT UNDERTAKING MODEL GRAVT AGREEMENT

ANNEX V - FORM C - FINANCIAL STATEMENT

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Total project eligible costs (4) (F1+G4)	6,765,547,62		
Total beneficiaries requested MI JJ contribution (4) (F3)	2,500,500,45		
Total EFPM companies in Aind constitution (6) (63)	3,192,040,21	Of which not-EU in Kind cover broken (4) 1,434,344,37	
Todal cantellautican (4) (P3 + 0-3)	8,748,103.48		
Total couls perisipant under Special Chuse 11 (H)	00.0	Of which Financial contribution from EFPIA companies (4) (H1)	0.00
Todal project costs (4) (F1+G1+H)	6,763,347.62		
Total intensits declared by the manufing entity of the Rill JJ funding	000		

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Annex V - Form C/ Summary Financial Report

## 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

In-house observation/findin	g	On-site observation	n/finding
Investigator Name:	Site No.:	Eudract No.:	IND/IDE No:
NA	NA	2015-003040-39	NA
Protocol No.:	Sponsor:	•	Date:
CTBM100G2202	Novartis Pharm	na	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

### Milestones

This is to document that the following milestones have been achieved:

- Site selection has been completed on 07 December 2016.
- First Patient Screened has been completed on02 February 2017.

Action required	d:	YES		NO	$\boxtimes$				
If yes, please describe (Include Action Plan Date / Action Due Date):									
Action complete	ed: Y	<b>YES</b>		NO					
If no, please describe (Include Completion Date):									

Signature								
Name	Function	Signature	Date					
Jens Lachmann	Project Manager	Lachmann, Jens enal-Jens Lachman Digitally signed by L DN: dc=com, dc=lco cn=Lachmann, Jens Digitally signed by L DN: dc=com, dc=lco cn=Lachmann, Jens Digitally signed by L DN: dc=com, dc=lco cn=Lachmann, Jens	ncr, ou=ICR, ou=Users, n@iconplc.com					





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