



## Model Driven Paediatric European Digital Repository

**Call identifier:** FP7-ICT-2011-9 - **Grant agreement no:** 600932

**Thematic Priority:** ICT - ICT-2011.5.2: Virtual Physiological Human

# Deliverable 4.3

## Report on Patient follow-up

**Due date of delivery:** October 31<sup>st</sup>, 2016

**Actual submission date:** December 30<sup>th</sup>, 2016

**Start of the project:** 1<sup>st</sup> March 2013

**Ending Date:** 28<sup>th</sup> February 2017

Partner responsible for this deliverable: UCL

Version: 2.0



<b>D4.3 Report on Patient follow-up</b>	<b>MD-Paedigree - FP7-ICT-2011-9 (600932)</b>
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**Dissemination Level:**

**Document Classification**

Title	<b>Report on Patient follow-up</b>
Deliverable	4.3
Reporting Period	4
Authors	Alex Jones
Work Package	4
Security	Public
Nature	Report
Keyword(s)	

**Document History**

Name	Remark	Version	Date
Alex Jones	First draft	1.0	27 November 2016
Alex Jones	Second draft, including contribution by other partners	1.1	9 December 2016
Davide Zaccagnini	Review	1.2	15 December 2016
Alex Jones	Final Version	2.0	21 December 2016

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## Clinical data & Routine laboratory test data collection

### Baseline data

Patient enrolment has been completed at OPBG and UCL. By M42 (*August 2016*), OPBG had enrolled 104 patients, with baseline imaging data in 84 patients (84 Echocardiography, 71 MRI and 104 ECG), and other baseline data in 104 patients. OPBG was required to enroll 80 patients at the baseline study. At that time, an extra sample of 24 patients was enrolled to compensate for the expected low patient retention rate in the follow-up study. Compliance of obese patients to long-term treatment is known to be poor, since most patients do not perceive their health condition as a life-threatening disease (Obesity 2012; 20:1319-1324; BMC Pediatr 2014; 19:14-53). The number of participants enrolled and the baseline data acquired and shared with the infrastructure are summarized in Table 1.

**Table 1. Baseline data collection**

	Data acquired (%)*	Data shared with infostructure (%)*
<b>Questionnaire</b>	104 (130%)	65 (81%)
<b>Anthropometry</b>	104 (130%)	80 (100%)
<b>Baseline bloods and cortisol</b>	104 (130%)	80 (100%)
<b>OGTT</b>	104 (130%)	80 (100%)
<b>Genetics bloods</b>	98 (116%)	90 (112%)
<b>ECG</b>	104 (130%)	80 (100%)
<b>Echocardiography</b>	84 (105%)	0 (0%)
<b>Whole Body fat</b>	71 (89%)	71 (89%)
<b>Baseline MRI</b>	71 (89%)	71 (89%)
<b>Stool microbiome</b>	75 (94%)	65 (81%)

(\* ) percentage based on 80 patients (expected target number for OPBG)

Echocardiograms have been acquired in 84 patients. Images of echocardiograms have been acquired and are in the process of being anonymized. Images of MRI have been acquired in 71 patients: 71 annotated, processed and shared. All ECG data have been acquired and shared with the Infostructure. The electronic case report forms (eCRF) for the questionnaires have been acquired in all patients and 65 eCRFs have been shared. For the estimation of adipokines, low-grade inflammation and insulin resistance: 104 assays stored for batch processing: 60 samples sent to Luminex for the analysis.

At UCL, enrollment was complete at the time of the previous report. Therefore, data are only briefly summarised again here. Table 2 summarises the data collection for UCL. As noted in previous reports, UCL participants completed a meal challenge protocol instead of a 1 year follow-up as was planned for OPBG and DHZB patients.

**Table 2. Baseline data collection**

	Data acquired (%)*	Data shared with infostructure (%)*
<b>Questionnaire</b>	82 (103%)	82 (100%)
<b>Anthropometry</b>	82 (103%)	82 (100%)
<b>Baseline bloods and cortisol</b>	82 (103%)	82 (100%)
<b>OGTT / meal challenge</b>	82 (103%)	82 (100%)
<b>Genetics bloods</b>	64 (80%) **	64 (100%)
<b>ECG</b>	82 (103%)	82 (100%)
<b>Echocardiography</b>	72 (90%)	72 (100%)
<b>Whole Body fat</b>	82 (103%)	82 (100%)
<b>Baseline MRI</b>	82 (103%)	82 (100%)
<b>Stool microbiome</b>	76 (95%)	52 (68%) ***

(\* ) percentage based on 80 patients (expected target number for UCL); (\*\* ) Some samples were lost due to incorrect processing in the genetics laboratory; (\*\*\*) Some samples awaiting laboratory processing.

DHZB have acquired and shared 8/20 full datasets (40) at baseline and no follow-up data.

## Follow up data (OPBG)

The follow up study still suffers from delay accrued at the beginning of the study. At the time of writing this report (M44), fifty-four patients out of 104 (51.2%) were lost to follow-up, while 50 (48.8%) patients agreed. In October 2016 (M44), follow-up data for 50 patients had been collected; Echocardiograms have been acquired in all patients. MRI has been acquired in 12 patients out of 50 (24%); the remaining patients did not undergo the magnetic resonance imaging (MRI) study but underwent all the other investigations, completing their follow-up. Some patients refused the follow-up MRI study because of too much discomfort or technical reasons e.g. dental implants. Table 3 summarises follow-up data collection at OPBG.

**Table 3. Follow-up data collection**

	Data acquired (%)*	Data shared with infostructure (%)*
<b>Questionnaire</b>	50 (100%)	0 (0%)
<b>Anthropometry</b>	50 (100%)	12 (24%)
<b>Blood sample</b>	50 (100%)	12 (24%)
<b>OGTT</b>	50 (100%)	12 (24%)
<b>ECG</b>	50 (100%)	0 (0%)
<b>Echocardiography</b>	50 (100%)	0 (0%)
<b>Whole Body fat</b>	12 (24%)	0 (0%)
<b>MRI</b>	12 (24%)	12 (24%)

(\*) percentage based on 50 patients

## Estimation of adipokines, low-grade inflammation and insulin resistance.

104 Assays stored for batch processing at OPBG, 60 sent to Luminex and 60 measures have been acquired; the remaining portion of the batch was unfortunately rendered unusable by a refrigeration issue which degraded the quality of the samples. The remaining set of samples were still utilized for the analysis the results of which will still be statistically significant. DHZB has performed all blood tests possible given the equipment available in Berlin. Therefore, some data are missing from that sources. UCL has acquired all samples at baseline and at multiple time-points following the meal challenge in 82/80 participants. All data have been laboratory processed except for GIP, Ghrelin and GLP-1, which will be completed by December.

## Image acquisition, clinical annotation, and data processing

Images have been acquired at UCL as per the full meal challenge protocol for 82/80 patients. At OPBG, 89% of participants at baseline (71/80) and 24% at follow-up have MRI data. Manual data processing at UCL is complete for flow measures and cardiac volumes in systole and diastole. Automated processing techniques are also being developed by the technical partners.

DHZB – Cardiac, vascular, and full body MRI sequences have been acquired in 8 patients.

## Systolic and diastolic markers of cardiac dysfunction of US and CMR

Available for all recruited patients at OPBG and UCL. DHZB has acquired cardiovascular sequences according to the study protocol.