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 3.1

Self-Assessment Plan

Due date of delivery:31-08-2013

Actual submission date:

Start of the project: 1st March 2013
Ending Date: 28th February 2017

Partner responsible for this deliverable: OPBG

Version: 1.2

Dissemination Level: Public

Document Classification

Title	Self-Assessment Plan
Deliverable	3.1
Reporting Period	1
Authors	Lynkeus
Work Package	WP1
Security	PU
Nature	RE
Keyword(s)	Self-Asssement criteria

Document History

Name	Remark	Version	Date
Mirko De Maldè		1.0	16 August 2013
Edwin Morley-Fletcher	Version circulated among all partners for revision	1.1	20 August 2013
Edwin Morley-Fletcher	Version which incorporates all partners' contributions	1.2	30 August 2013

List of Contributors

Name	Affiliation
Lorenza Putignani	OPBG
Sonya Martin	OPBG
Gabriele Rinelli	OPBG
Clara Malattia	IGG
Maria Cristina Ferrari	IGG
Stefano Lanni	IGG
Marije Goudriaan	KULeuven
Kaat Desloovere	KULeuven
Alex Jones	UCL
Marjiolen van der Krogt	Vumc
Tobias Heimann	SIEMENS
Harry Dimitropoulos	ATHENA
Omiros Metaxas	ATHENA
Frans Steenbrink	MOTEK
Karl Stroetmann	EMPIRICA
Edwin Morley-Fletcher	LYNKEUS
Mirko De Maldè	LYNKEUS

List of reviewers

Name	Affiliation
Bruno Dallapiccola	OPBG
Edwin Morley-Fletcher	LYNKEUS
Sonya Martin	OPBG
Xavier Pennec	OPBG
Alexey Tsymbal	SIEMENS
Karl Stroetmann	EMPIRICA
Henning Muller	HES-SO
David Manset	MAAT
Patrich Ruch	HES-SO

Table of Contents

Short Description of this Deliverable 5

Methodological Note 5

WPs performance indicators and self-assessment plans 5

The Scientific Committee Project Review. 5

Yearly re-definition of the Self-Assessment plan 6

Rationale of the project's work breakdown structure (per activities) 6

WPs' Self-Assessment Plans 8

A4- WP1 8

A1- WP2 10

A1- WP3 11

A1 - WP4 13

A1 - WP5 14

A1- WP6 15

A2 - WP7 17

A2- WP8 18

A2- WP9 19

A2- WP10 20

A2- WP11 21

A1 - WP12 22

A3- WP13 23

A3- WP14 25

A3- WP15 27

A2- WP16 28

A2- WP17 30

A4- WP18 31

A4- WP19 32

Short Description of this Deliverable

The Self Assessment indicators have been used by all WP leaders while preparing the first Half-Yearly Activity Report: the progress against self assessment plan has been declared in each workpackage.

Methodological Note

The self-assessment plan of the MD-Paedigree project results from a joint effort of all consortium partners. Both the Action Leaders and the Work Package Leaders (WPLs) have been involved in defining modes and characteristics for the self-assessment of the different activities which have been planned within the MD-Paedigree project.

The set indicators, updated whenever necessary, will be monitored 1-2 months before the end of each annual reporting period, in order to make them serve as a specific tool for progress reporting within the project management activity provided for to the Consortium by the Project Coordinator and the Project Manager.

WPs performance indicators and self-assessment plans

As a first input, each of the WP Leaders has been requested to clarify the main objectives each respective WP aims to achieve – specifying and describing the activities which are deemed necessary for achieving the designated objectives.

As an intermediate step, a description of the measurement processes/methodologies which were adopted by the various WPLs was also requested, in order to make it possible to self-assess the results achieved carrying on the activities associated with the above mentioned WP objectives.

Finally, and on the basis of the previous inputs, a series of correlated indicators for measuring the outcomes of the various WP activities has been defined, associating them, as much as possible, to task-level details with an approximate numerical indication of the allowed threshold limits related to each WP objective.

The format of the WP benchmarking assessment template used for these purposes as well as the various WP inputs provided for by WPLs were included in the following section of this document.

In their inputs, WPLs have included qualitative (subjective) and quantitative (objective) indicators. While qualitative scales usually range between 1 and 5, with level 5 being the most satisfying achievement of each task's goal, quantitative indicators are related to well-defined measurement processes and measurement units.

The Scientific Committee Project Review.

The Scientific Committee (SC) organizes a Scientific Project Review (SPR) about 1-2 months before the annual Technical Review (EC review). Following the scientific review, the SC will produce a set of documents assessing the current scientific status of the project.

Among the various SC functions, as described in the DoW, the following ones are of particular relevance:

"…- Assess technical progress by comparing the project results to the state-of-the-art;

- Periodically organise sessions for auditing and evaluating the research performed;
- Stipulate and evaluate measurable results for project activities; …"

Taking into account these functions, the Scientific Project Review might also include suggestions for adopting different or improved self-assessment criteria. The SPR will be handed over to the Governing Board, which shall implement, if necessary, suitable changes and use, if appropriate, the new release of self-assessment criteria in the Reports submitted to the Commission.

Yearly re-definition of the Self-Assessment plan

It is the WPLs' common belief that the Self Assessment plan must be considered as a dynamic process, undergoing appropriate updating every year in order to validate/modify the chosen indicators, also on the basis of the SC yearly evaluation.

Rationale of the project's work breakdown structure (per activities)

For a better understanding of the project's objectives we refer to the work breakdown structure:

A1: Clinical background activities, user requirements, clinical workflow and validation

Led by Giacomo Pongiglione (OPBG)

WP2 – Clinical and technical user requirements for disease modeling, led by Marcello Chinali

WP3 – Data acquisition and processing for Cardiopyopathies, led by Gabriele Rinelli

WP4 – Data acquisition and processing for CVD risk in obese children, led by Andrew Taylor

WP5 – Data acquisition and processing for JIA, led by Alberto Martini

WP6 – Data acquisition and processing for NND, led by Jaap Harlaar

WP12 – Models validation, outcome analysis, and clinical workflows, led by Giacomo Pongiglione

A2: Modelling and Simulation - Led by Tobias Heimann (SAG)

WP7 – Genetic and metagenomic data analysis, led by Bruno Dallapiccola

WP8 – Modeling and simulation for Cardiomyopathies, led by Tobias Heimann

WP9 - Modeling and simulation for CVD risk in obese children, led by Alexey Tsymbal

WP10 - Modeling and simulation for JIA, led by Marco Viceconti

WP11 - Modeling and simulation for NND, led by Frans Steenbrink

A3: MD-Paedigree Infostructure Led by David Manset (MAAT)

WP13 – Clinical and technical requirements for MD-Paedigree infostructure and compliance analysis, led by Henning Muller

WP14 – Grid-Cloud Services provision and GPU services integration, led by David Manset

WP15 – Semantic data representation and integration and ontology based Data Access and query formulation, led by Patrick Ruch

WP16 - Biomedical Knowledge Discovery and Simulation for Model-guided Personalised Medicine, led by Yannis Ioannidis,

WP17 – Testing and validation, led by Yannis Ioannidis,

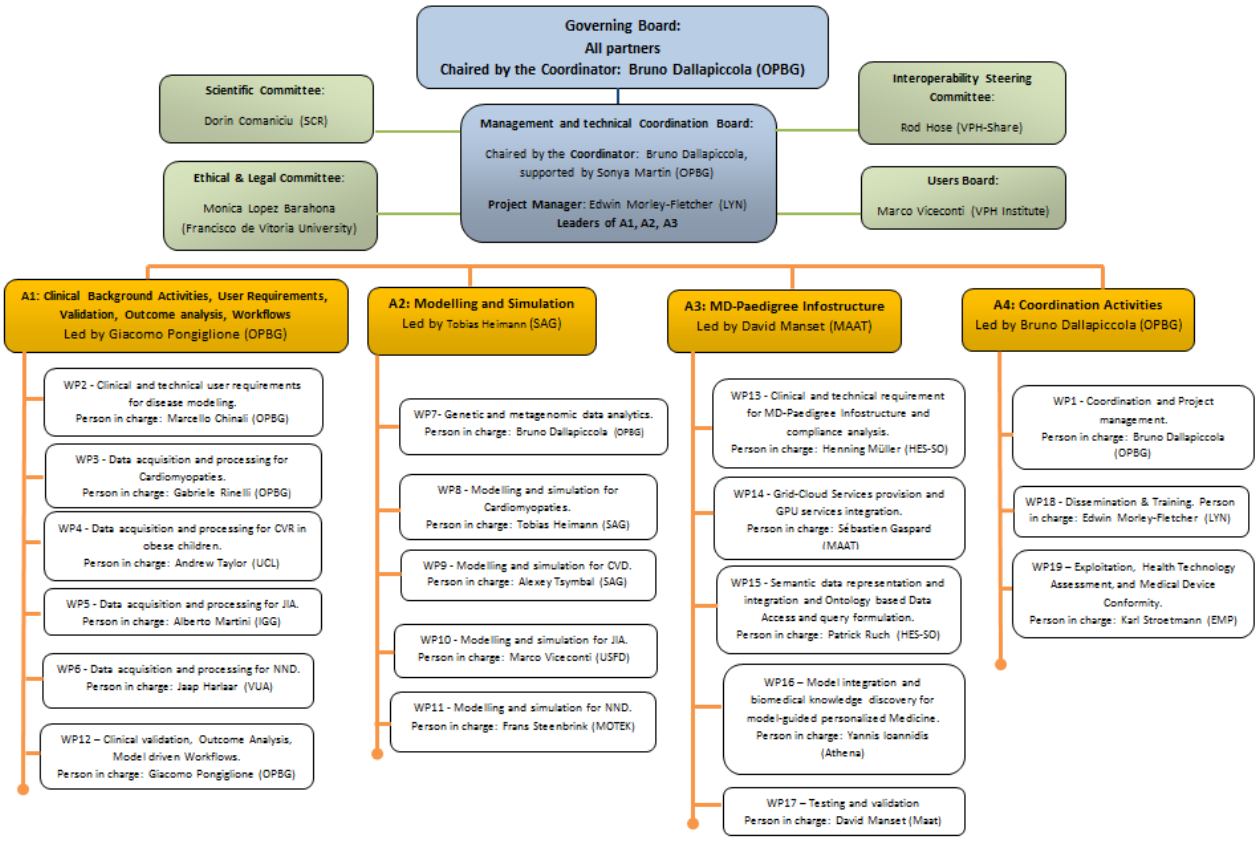
A4 – Coordination activities led by Bruno Dallapiccola (OPBG)

WP1 – Coordination and Project Management, led by Bruno Dallapiccola

WP18 – Dissemination and Exploitation, led by Edwin Morley-Fletcher

WP19 – HTA and medical clearance, led by Karl Stroetmann

Graphical presentation of the Activities grouping the various WPs



WPs' Self-Assessment Plans

A4- WP1 Coordination & Project Management			
Lead Partner:	**OPBG**	**WP Leader**:	Bruno Dallapiccola
Objective N°	**Task**	**Objectives' Description**	
1.1	T1.1	Timely completion of activities in each single WP.	
1.2	T1.2	Providing quality assurance guidelines, outlining project timing, quality procedures, deliverables production procedures, and ethical procedures.	
1.3	D.1.5/D1.6	Reporting of project activities and progress.	
1.4	T1.3	Effective handling of all financial matters arising during the course of the project.	
1.5	T1.4	Effective handling and resolution of all contractually relevant or partner conflict situations.	
1.6	T1.5/T1.6	Efficient organising, planning and reporting on all meetings envisioned in the project plan, and providing the project communication infrastructure.	
1.7	T1.7	Clustering and concertation effort to interact with other relevant EC-funded projects and NoEs. Partecipation to relevant meeting organized by EC.	
1.8	T1.8	Effective recruiting independent experts from institutions internal and external to the consortium members to staff the Scientific Committee and the Ethical and Legal Review Committees.	
1.9	T1.9	Identification, assessment, and prioritization of potential risks.	
1.10	T1.10	Monitor and review project deliverables authorizing release where ethical questions arise and monitor for upcoming ethical and legal implications.	

Measurement	
Objective N°	**Measurement Process and units**
1.1	Percentage of activity completion by deadline.
1.2	Availability of Self-Assessment and other quality guidelines.
1.3	Number days in advance/delay against delivery deadline.
1.4	Percentage of completion/update of input of financial data.
1.5	Percentage of solved/unsolved requests relevant to Grant/Consortium Agreement amendments; percentage of solved/unsolved partners' conflicts.
1.6 -1	Percentage of planned meetings organised during each Reporting Period.
1.6 -2	Number of Users registered to the Communication platform.
1.7	Percentage of participating actions on possible opportunities.
1.8	Recruiting Time.
1.9	Potential risks identified and assessed during each reporting period.
1.10	Effective handling of ethical issues raised during each reporting period.

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable)**
1.1	100%	50%
1.2	Self-Assessment available within month 6; quality guidelines available within month 8	Self-Assessment available within month 8; quality guidelines available within month 10
1.3	+15 days	+45 days
1.4	100%	75%
1.5	100%	50%
1.6 -1	100%	50%
1.6 -2	50	25
1.7	100%	50%
1.8	6 months	12 months
1.9	100%	50%
1.10	100%	50%

A1- WP2 Clinical and technical user requirements for disease modeling			
Lead Partner:	OPBG	WP Leader:	Marcello Chinali
Objective N°	**Task**	Objective's Description	
2.1	T.2.1	Requirements elicitation and documentation	
2.2	T.2.2	Revised requirements analysis document	
2.3	T.2.2	Update on the requirements document: Follow-up Data Collection, Advanced Prototypes, Evaluation and Requirements	

Measurements	
Objective N°	Measurement Process and units
2.1 - 1	Number of interviews with clinical and technical partners
2.1 - 2	Percentage of completition of initial requirements' analysis document
2.2	Percentage of requirements revised
2.3	Percentage of update on the requirements' document

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	Upper limits (result's maximum expectation)	Lower Limits (below which result is not acceptable)
2.1 -1	100% by Month 12	75% Month 12
2.2 -2	100% by Month 12	75% by Month 12
2.2	100% by Month 24	75% by Month 24
2.3	100% by Month 36	75% by Month 36

A1- WP3 Data acquisition and processing for Cardiopyopathies			
Lead Partner:	**OPBG**	**WP Leader**:	Gabriele Rinelli
Objective N°	**Task**	**Objectives' Description**	
3.1	T.3.1	Definition of Data Collection Protocol	
3.2	T.3.1	Implementation of the Informed Consent Forms	
3.3	T.3.2	Clinical data & Routine laboratory test Data collection at month 16	
3.4	T.3.2	Clinical data & Routine laboratory test Data Collection at month 22	
3.5	T.3.2	Clinical data & Routine laboratory test Data collection at month 28	
3.6	T.3.2	Clinical data & Routine laboratory test Data Collection at month 34	
3.7	T.3.3	Estimation of functional class and cardiopulmonary tests at month 22	
3.8	T.3.3	Estimation of functional class and cardiopulmonary tests at month 34	
3.9	T.3.4	Imaging Acquisition at month 16	
3.10	T.3.4	Imaging Acquisition at month 22	
3.11	T.3.4	Imaging Acquisition at month 28	
3.12	T.3.4	Imaging Acquisition at month 34	
3.13	T.3.5	Data processing	

Measurement		
Objective N°	**Measurement Process and units**	
3.1	Availability of Protocol	
3.2	Availability of Informed consent Forms	
3.3	Percentage of clinical data and routine laboratory test collection	
3.4	Percentage of clinical data and routine laboratory test collection	
3.5	Percentage of clinical data and routine laboratory test collection	
3.6	Percentage of clinical data and routine laboratory test collection	
3.7	Percentage of functional class and cardiopulmonary tests performed	
3.8	Percentage of functional class and cardiopulmonary tests performed	
3.9	Percentage of Imaging Acquisition	
3.10	Percentage of Imaging Acquisition	
3.11	Percentage of Imaging Acquisition	
3.12	Percentage of Imaging Acquisition	
3.13	Quality and usability of collected data	

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable)**
3.1	Protocol ready by Month 3	Complete draft Protocol not ready by month 3
3.2	Informed consent Forms Available by Month 3	Complete draft Informed consent Forms not Available by Month 6
3.3	25%	10%
3.4	50%	25 %
3.5	75%	60%
3.6	100%	75%

3.7	50%	25 %
3.8	100%	75%
3.9	25%	10%
3.10	50%	25 %
3.11	75%	60%
3.12	100%	75%
3.13	90 % Data fully usable for modelling purposes	< 90% Data not usable for modelling purposes

A1 - WP4 Data acquisition and processing for CVD risk in obese children			
Lead Partner:	**UCL**	**WP Leader**:	Andrew Taylor
Objective N°	**Task**	**Objectives' Description**	
4.1	T4.1	Definition of data collection protocol	
4.2	T4.1	Implementation of the Informed Consent Forms	
4.3	T4.1	Alignment of MR obesity and vascular sequences between centres	
4.4	T4.2	Clinical data collection & Routine laboratory test data collection	
45	T4.3	Estimation of adipokines, low-grade inflammation and insulin resistance [M 5-36]	
4.6	T.4.4	Image acquisition, clinical annotation and data processing	
4.7	T.4.5	Systolic and diastolic markers of cardiac dysfunction of US and CMR	
4.8	T.4.6	Measurement of arterial compliance and reactive hyperaemia [5-40]	

Measurement	
Objective N°	**Measurement Process and units**
4.1	Availability of Protocol
4.2	Availability of Informed Consent Forms
4.25	Agreed imaging protocols for all centres with available sequences
4.3	Percentage of completion of Clinical Data Collection
4.4	Measurements of adipokines and markers of inflammation, Assessment of the renin-angiotestin-aldosterone axes, insulin resistance estimation
4.5	Percentage of Image acquired and annotated and processed
4.6	Percentage of data acquisition of systolic and diastolic markers of cardiac dysfunction of US and CMR
4.7	Percentage of completion of vascular measures

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable**)
4.1	Ready by by Month 4	Draft ready by Month 3
4.2	Ready by Month by Month 4	Draft readyby Month 3
4.25	Ready by month 11	Ready by month 9
4.3	60% by Month 24	20% by Month 12 (36 Patients)
4.4	100% by Month 36	10% by Month 12 (18 Patients)
4.5	60% by Month 24	40% by Month 24
4.6	60% by Month 24	40% by Month 24
4.7	60% by Month 24	40% by Month 24

A1 - WP5

Data acquisition and processing for JIA

Lead Partner:	IGG	WP Leader:	Alberto Martini

Objective N°	Task	Objectives' Description
5.1	T.5.1	Definition of data collection protocol and Implementation of the Informed Consent Forms
5.2	T.5.2	Clinical data collection
5.3	T.5.3	Routine laboratory tests
5.4	T.5.4	Synovial and blood Cytokine and inflammatory mediators profile
5.5	T5.5	Metagenome data analysis (gut microbiota)
5.6	T.5.6	Image acquisition and clinical annotation
5.7	T.5.7	Gait cycle analysis [M 4-40]

Measurement

Objective N°	Measurement Process and units
5.1	The study protocol and informed consents forms have been approved by the local ethical committee in all three centres. Units: number of centres.
5.2	Patients have been enrolled and followed-up until 2 years. Units: number of patients that have been enrolled and of whom data has been collected.
5.3	Routine blood samples have been collected in the enrolled patients. Units: number of patients of whom blood has been drawn.
5.4	Cytokine and inflammatory mediators profile has been made for each patient. Units: number of patients for which a profile has been made.
5.5	Metagenome data analysis has been performed for each patient. Units: number of patients which have been assessed.
5.6	All imaging procedures have been performed in all patients, if applicable (depending on ankle involvement). Units: number of patients.
5.7	GCA has been performed in all patients with clinical involvement of the ankle. Units: number of patients.

Indicators [Upper and lower limits associated with WP objectives and measurement units]

Objective N°	Upper limits (result's maximum expectation)	Lower limits (below which result not acceptable)
5.1	3	<3
5.2	200	<130
5.3	200	<130
5.4	200	<100
5.5	200	<100
5.6	200	<130
5.7	30	10

A1- WP6 Data acquisition and processing for NND			
Lead Partner:	**VUmc**	**WP Leader**:	Jaap Harlaar
Objective N°	**Task**	**Objectives' Description**	
6.1-1	T6.1	Q&A on data collection and clinical protocols	
6.1-2	T6.1	Definition of standard clinical protocol for CGA	
6.2	T6.2	Gait analysis collection for CP	
6.3	T6.3	Gait analysis collection for DMD and SMA	
6.4	T6.4	Image acquisition	

Measurement	
Objective N°	**Measurement Process and units**
6.1 -1	Completion of clinical protocol description in each clinical centres and of QA analysis
6.1 -2	Number of CGA laboratories involved in the survey to establish a EU inventory on the protocols for CGA
6.1 -3	CGA standard protocol established
6.2 -1	Number of data sets available by month 18
6.2 -2	Number of retrospective datasets available by month 36
6.3	Number of data sets available by month 18
6.4 -1	Number of image acquisition by month 18
6.4 -2	Number of MRI data from healthy children by month 12
6.4-3	Number of DXA data from healthy children by month 12

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable)**
6.1 -1	100% by month 8	75% by month 18
6.1 -2	10	5
6.1 -3	CGA protocol established by month 8	CGA protocol established by month 18
6.2 -1	Data sets from 15 CP patients for biophysical modelling.	Data sets from 10 CP patients for biophysical modelling.
6.2 -2	Data sets from 75 CP patients for probabilistic modelling (pre + post treatment).	Data sets from 35 CP patients for probabilistic modelling (part of this pre-post treatment).
6.2 -3	Retrospective datasets of 300 CP patients for probabilistic modelling (pre+post treatment).	Retrospective datasets of 150 CP patients for probabilistic modelling (part of this pre+post treatment).
6.3 -1	Baseline data collection of 20 SMA patients completed	Baseline data collection of 15 SMA patients completed
6.3 -2	Baseline data collection of 20 DMD patients completed	Baseline data collection of 15 DMD patients completed
6.4 -1	Paired DXA and MRI data sets from 15 CP patients	Paired DXA and MRI data sets from 10 CP patients
6.4 -2	30 MRI data sets of healthy children	10 MRI data sets of healthy children

6.4 -3	20 DXA scans of healthy children	15 DXA scans of healthy children

A2 - WP7 Genetic and metagenomic data analysis			
Lead Partner:	**OPBG**	**WP Leader**:	Bruno Dallapiccola
Objective N°	**Task**	**Objectives' Description**	
7.1	T7.1	Definition of data collection protocol	
7.2	T7.1	Implementation of the Informed Consent Forms	
7.3	T7.2 & T7.3	Sample collection, storage and DNA extraction and analysis - cardiology	
7.4	T7.2 & T7.3	Sample collection, storage and DNA extraction and analysis - cardiovascular risk in obesity	
7.5	T7.2 & T7.3	Sample collection, storage and DNA extraction and analysis - rheumatology	
7.6	T7.2 & T7.3	Sample collection, storage and DNA extraction and analysis – control group	

Measurement		
Objective N°	**Measurement Process and units**	
7.1	Availability of Recruitment protocol	
7.2	Availability of Informed consent Form	
7.3	Number of samples collected by month 18	
7.4.1	Number of gut microbiote samples (stools) collected at each clinical site by month 18: a) shipping them to the OPBG for DNA extraction b) performing on site the DNA extraction	
7.4.2	Number of blood samples collected, and DNA extraction, performed at each clinical site by month 18, shipping the DNA to BMR Genomics	
7.5.1	Number of gut microbiote samples (stools) collected at each clinical site by month 18: a) shipping them to the OPBG for DNA extraction b) performing on site the DNA extraction	
7.5.2	Number of blood samples collected, and DNA extraction, performed at each clinical site by month 18, shipping the DNA to BMR Genomics	
7.6	Number of samples collected by month 18	

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable)**
7.1	Available by month 3	Available by month 4
7.2	Available by month 3	Available by month 4
7.3	90	60
7.4.1	50	40
7.4.1 a)	25	20
7.4.1 b)	25	20
7.4.2	50	40
7.5.1	**70**	**50**
7.5.1 a)	35	25
7.5.1 b)	35	25
7.5.2	80	60
7.6	50	30

A2- WP8 Modelling and simulation for Cardiomyopathies			
Lead Partner:	**SIEMENS**	**WP Leader**:	Tobias Heimann
Objective N°	**Task**	**Objectives' Description**	
8.1	T.8.1	Derive the complete patient-specific anatomical and dynamical model of the heart from MRI / echo data, including chambers, valves and main vasculature, and integrate structural data from adapted atlases.	
8.2	T.8.2	Create patient-specific electromechanical models of the heart coupled with arterial circulation for a comprehensive analysis of cardiomyopathy and therapy outcome prediction.	
8.3	T.8.3	Provide blood flow simulation of the entire heart and corresponding validation with respect to measurements from medical images	
8.4	T.8.4	Create patient-specific multiscale and multiphysics models of the whole heart, both healthy and affected by cardiomyopathies, by integrating the anatomical and haemodynamical representation with biomechanical and electrophysiological models.	
8.5	T.8.5	Analyze the shape of the subject-specific anatomy statistically to infer information about disease progression.	

Measurement		
Objective N°	**Measurement Process and units**	
8.1	Percentage of completion within month 10	
8.2	Percentage of completion within month 10	
8.3	Percentage of completion within month 10	
8.4	Percentage of completion within month 10	
8.5	Percentage of completion within month 10	

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable)**
8.1	15%	8%
8.2	15%	8%
8.3	15%	8%
8.4	0%	0%
8.5	15%	8%

A2- WP9 Modelling cardiovascular risk in the obese child and adolescent			
Lead Partner:	**SIEMENS**	**WP Leader**:	Alexey Tsymbal
Objective N°	**Task**	**Objectives' Description**	
9.1	T.9.1	Adaptation of the comprehensive heart model of WP8 to the obese heart;	
9.2	T.9.2	Automated estimation of the distribution of various adipose tissue types from MRI and ultrasound data;	
9.3	T.9.3	Determination of factors contributing to the risk	
9.4	T.9.4	Construction of personalised multivariate retrieval-based models for the assessment of cardiovascular risk and therapy selection support	

Measurement		
Objective N°	**Measurement Process and units**	
9.1	Percentage of completion within month 24	
9.2	Percentage of completion within month 24	
9.3	Percentage of completion within month 24	
9.4	Percentage of completion within month 24	

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable)**
9.1	70%	40%
9.2	35%	15%
9.3	35%	15%
9.4	35%	15%

A2- WP10 Modelling and simulation for JIA			
Lead Partner:	**USFD**	**WP Leader**:	Marco Viceconti
Objective N°	**Task**	**Objectives' Description**	
10.1	T.10.1	Development of articulated models of the JIA affected joints	
10.2	T.10.2	Automatic extraction of biomarkers	
10.3	T.10.3	Patient-specific biomechanical simulation	
10.4	T.10.4	Multidimensional modelling of the disease course	

Measurement		
Objective N°	**Measurement Process and Units**	
10.1	Individualised model for each patient of three cohorts: contralateral healthy control, affected in remission at 6m, affected severe at 12m. **Measurement Unit:** number of patients x cohort	
10.2	Percentage of completion within month 24	
10.3	Biomechanical determinants are predictors of the side and/or of the severity. **Measurement Unit:** Power of the statistical test used to test the hypothesis	
10.4	One case will be modelled 5 times, blindly to the operator, in order to assess the repeatability of the modelling chain. **Measurement Unit:** variance over 5 repetitions.	

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable**)
10.1	30	10
10.2	50%	35%
10.3	PI=0.8	PI=0.6
10.4	<10%	<25%

A2- WP11 Modelling and simulation for NND			
Lead Partner:	**MOTEK**	**WP Leader**:	Frans Steenbrink
Objective N°	**Task**	**Objectives' Description**	
11.1-1	T.11.1	Evaluate test MRI from T6.4	
11.1-2	T.11.1	Method to generate subject specific mass distribution models for the lower limbs from DXA images.	
11.1	T.11.1	Extraction of subject-specific bone and muscle anatomy from DXA and MRI images	
11.2-1	T.11.2	Review available scaling methods	
11.2-2	T.11.2	Define pipe-line to implement different scaling method.	
11.2-3	T.11.2	Implement option for different scaling method in HBM	
11.3-1	T.11.3	Adaptation of the kinematic model (anatomical calibration, functional axis, more degrees of freedom in knee/ankle, parameterized bone deformaties)	
11.3-2	T.11.3	Calculation of muscle lengths based on parameterized deformities	
11.3-3	T-11.3	Muscle attachment sites based on MRI/DXA	
11.3-4	T-11.3	Adaption of existing musculoskeletal model to subject-specific and pathology specific data.	
11.4	T.11.4	Design of models driven by the dynamics of gait perturbations.	

Measurement		
Objective N°	**Measurement Process and units**	
11.1	Percentage of completion within month 24	
11.2	Percentage of completion within month 24	
11.3	Percentage of completion within month 24	
11.4	Percentage of completion within month 24	

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable)**
11.1	70%	40%
11.2	35%	15%
11.3	35%	15%
11.4	15%	5%

A1 - WP12 Models validation, outcome analysis, and clinical workflows			
Lead Partner:	**OPBG**	**WP Leader**:	Giacomo Pongiglione
Objective N°	**Task**	**Objectives' Description**	
12.1	T12.1	Clinical Assessment And Validation	
12.2	T12.2	Integrated Clinical Workflows	
12.3	T12.2	Personalised Treatment Models	

Measurement		
Objective N°	**Measurement Process and units**	
12.1	Percentage of completion of the Clinical Assessment of cardiomyopathy models, obesity models, and musculoskeletal biomechanic models (JIA and NND).	
12.2	Percentage of completion of new clinical workflows for cardiomyopathy, CVR in obese children, in JIA, for NND	
12.3	Personalised Treatment Models	

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable**)
12.1	100% by month 48	75% by month 48
12.2	100% by month 48	60% by month 48
12.3	Ready by month 48	First tests successfully performed by month 48

A3- WP13 Requirements and Compliance for the MD-Paedigree Infostructure			
Lead Partner:	**HES-SO**	**WP Leader**:	Henning Muller
Objective N°	**Task**	**Objectives' Description**	
13.1	T.13.1	Interviews with clinical and research partners to enable the generation of a complete list of requirements.	
13.2	T.13.1	The requirements must be prioritized in order of importance in order to ensure the quick development of an operational system.	
13.3	T13.1	Focus groups organized with at least three different partners (cardiologist, geneticist, infrastructure expert, ...) to come up with requirements and priorization across disciplines.	
13.4	T13.2	Regular contact with stakeholders to update requirements and change the priorities if necessary. These updates can also be used to modify data requirements.	
13.5	T13.2	The infostructure must be designed such that all requirements relating to OpenAIRE and VPH-Share are taken into account.	
13.6	T13.2	Contact with VPH users and participants to measure acceptance of the developed tools once per year after the initial prototype.	
13.7	T13.3	VPH-Share community partners within and outside MD PAEDIGREE must have long-term access to all data obtained during the project.	
13.8	T13.3	In addition to consistent formatting and storage of data across platforms, interoperatibility at the semantic level must be ensured in order to allow effective indexing and searching through collected data.	
13.9	T13.3	All project output from MD PAEDIGREE must be accessible from within VPH-Share and vice versa, tests run at least once per year.	
13.10	T13.4	Schemes for making data and publications associated with the infostructure compliant with existing European efforts and policies must beinvestigated.	
13.11	T13.4	Data exploration by 3rd parties must be improved by following OpenAIRE and OpenAIREplus metadata guidelines.	
13.12	T13.4	Workshops or networking or training sessions must be organized such that both researchers and clinicians have an opportunity to explore win-win situations arising from the open sharing of scientific information preferably in connection with existing meetings.	

Measurement		
Objective N°	**Measurement Process and units**	
13.1	Number of Interviews.	
13.2	Number of requirements prioritized.	
13.3	Number of focus group organised.	
13.4	Number of contact with stakeholders per year.	
13.5	Number of successful tests of this compatibility per year.	
13.6	Percentage of users' acceptance of the developed tools.	
13.7-8-9	1 - The infostructure is only partially accessible and interoperability of data is not fully guaranteed. 5 - The infostructure is fully accessible by the VPH-Share community and full interoperability at the semantic level is ensured allowing effective indexing and searching through collected data.	

13.10	Number of technology tests and analysis.
13.11	Compliance with openAIRE metadata quidelines.
13.12	Number of workshops organised per year.

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable**)
13.1	8	5
13.2	75	50
13.3	3	1
13.4	6	4
13.5	3	1
13.6	75%	50%
13.7-8-9	5	3
13.10		at least once per year
13.11	100%	30%
13.12	2	1

A3- WP14 Clinical and technical user requirements for disease modeling			
Lead Partner:	**MAAT**	**WP Leader**:	David Manset
Objective N°	**Task**	**Objectives' Description**	
14.1	T14.1	The grid network is installed and configured for MD-Paedigree.	
14.2	T14.1	Load Capacity analysis is provided.	
14.3	T14.1	The number of gateway corresponds to what the analysis defines / the workload is supported / the application of WP15 and 16 are compatible with the system.	
14.4	T14.2	Cloud provider and APIs have been chosen and qualified to be integrated the MD-Paedigree solution / GPU computing Technology has been chosen for the GPU processing layer.	
14.5	T14.2	All the application from WP15-16 can be deployed onto the cloud / the imaging calculation solution from WP15-16 can run using GPU.	
14.6	T14.3	ADP is integrated into the infostructure providing distributed querying and data management capabilities over existing federated heterogeneous datasources	
14.7	T14.3	ADP is integrated into the system providing distributed processing and parallelization of resourse/time consuming algorithms	
14.8	T14.4	VPH-Share recommendations that the solutions have to follow are defined for all the application.	
14.9	T14.4	All the applications that are developed for MD-Paedigree (in particular the ones from WP15-16) respect the VPH-Share defined recommendations and will manage to use Pandora security, privacy and integration functionalities to be servable as a service through the gateways.	

Measurement		
Objective N°	**Measurement Process and units**	
14.1	Percentage of completion	
14.2	Percentage of completion	
14.3	Percentage of completion (full operability)	
14.4	Percentage of completion	
14.5	Percentage of completion	
14.6	Percentage of completion	
14.7	Percentage of completion	
14.8	Percentage of completion	
14.9	Percentage of completion	

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable)**
14.1	100% within Month 6	75% within Month 6
14.2	100% within Month 9	75% within Month 9
14.3	100% within Month 12	50% within Month 12
14.4	100% within Month 12	75% within Month 12
14.5	100% within Month 12	50% within Month 12

14.6	50% within Month 18	30% within Month 18
14.7	50% within Month 18	30% within Month 18
14.8	100% within Month 12	50% within Month 12
14.9	50% within Month 12	20% within Month 12

A3- WP15 Semantic Data Representation and Information access			
Lead Partner:	**HES-SO**	**WP Leader**:	Patrick Ruch
Objective N°	**Task**	**Objectives' Description**	
15.1	T15.1	Data curator and Validator (DCV) tool enhanced with intelligent data curation mechanisms, integrated with query engine API and madIS	
15.2	T15.3	First prototype for the case- and ontology-based retrieval service	
15.3	T15.4	Final prototype of a multimodal case- and ontology-based retrieval service	

Measurement		
Objective N°	**Measurement Process and units**	
15.1	1 - DCV curation tool still not fully operational. 2 - DCV integrated with madIS and with all basic curation & validation functionality operational, but without the advanced/inteliigent (semi-)automatic curation mechanisms. 3 – Fully operational DCV curation tool with advanced semi-automatic/intelligent curation mechanisms utilizing user feedback 4. Publish a related API that allows integration with external services/tools making available high quality data curation techniques over existing data sources.	
15.2	The first prototype makes services available for the case- and ontology–based retrieval, so these can be integrated in the infostructure by month 24.	
15.3	The multimodal case- and ontology-based retrieval service, powered with relevance feedback, is fully operational: the application will receive as input a user information request. The service will output similar cases. It will use these similar cases to suggest refinements in order to reformulate the input query.	

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable)**
15.1	1&2 within month 24, 3&4 within month 48	2 within month 24
15.2	100% within month 24	75% within month 24
15.3	50% within month 24	35% within month 24

A2- WP16 Biomedical Knowledge Discovery and Simulation for Model-guided Personalised Medicine			
Lead Partner:	**ATHENA**	**WP Leader**:	Omiros Metaxas
Objective N°	**Task**	**Objectives' Description**	
16.1	T.16.1	General data analysis and knowledge discovery tools integrated with the infostructure platform	
16.2	T.16.2	Incorporate PAROS Personalisation Platform for personalized querying	
16.3	T.16.2	Incorporate PAROS Personalisation Platform for patient & disease profile modeling	
16.4	T.16.3	AITION Knowledge Discovery & Simulation Framework integrate with the infostructure platform	
16.5	T.16.5	Data-driven drug and trial design	

Measurement		
Objective N°	**Measurement Process and units**	
16.1	1. Develop simple data analysis and KDD tools addressing well defined research tasks capturing specific user requirements such as: a. high dimensionality reduction and feature selection, b. similarity analysis & c. clustering 2. Integration with DCV data preprocessing engine 3. Integration with the Infostructure platform addressing related security, data retrieval and results saving issues 4. CaseReasoner integration 5. Develop a fully integrated platform with one WEB based GUI for data analysis and KDD 6. Big Data analytics support based on scalable data analysis techniques and distributed execution 7. Scientific Workflow engine encapsulation that will support scalable and reproducible scientific research, as well as interdisciplinary collaboration across different institutions and scientists.	
16.2	1. Tools for manual user profile definition. 2. Integration with Ontology Based Access task supporting Personalized Querying and results adaptation. 3. Semi automated user profile generation analyzing user logs or other sources and capturing specific usage patterns	
16.3	1. Tools for patient and disease specific modeling & exploration capturing high-level concepts and common characteristics 2. Integration with general & AITION KDD platforms, as well as, other external tools (eg HES-SO KRESHMOI)	
16.4	1. WEB based GUI for reasoning based on PGMs. Researcher will be able to run multiple statistical simulation (what if) scenarios based on already defined PGMs based models. 2. Integration with the Infostructure platform addressing related security, data retrieval and results saving issues.	

	3. Integration with DCV data preprocessing engine 4. WEB based GUI with advanced functionalities for all tasks related to PGMs based learning. Researcher will be able to analyze data, discover hierarchical dependencies between variables & generate related DAG. 5. Big Data analytics support based on scalable data analysis techniques and distributed execution that will support analysis of thousand of variables / measurements. 6. More advance model learning techniques incorporating external knowledge and user defined constraints. 7. Integration with patient disease specific profiles from PAROS personalization engine 8. Integration with general KDD platform and (if exist) encapsulated Scientific Workflow engine.
16.5	1. Development of a simple user interface to assess the feasibility of already existing clinical protocols 2. Development of an advanced user interface to assess the feasibility of already existing clinical protocols: possibility to refine/relax criteria 3. Development of a model to identify any association between a set of data and any other data (e.g.: a doctor who wants to know what is associated with "age+diagnosis+drug"? => co-morbitities, SNPs, vital signs, etc.)

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable**)
16.1	1-7 by month 48	1-4 by month 48
16.2	1-3 by month 48	1-2 by month 48
16.3	1-2 by month 48	1 by month 48
16.4	1-8 by month 48	1-3 by month 48
16.5	1-3 by month 48	1 by month 48

A2- WP17 Testing and validation			
Lead Partner:	**ATHENA**	**WP Leader**:	Harry Dimitropoulos
Objective N°	**Task**	**Objectives' Description**	
17.1	T17.1	MD-Paedigree Infrastructure testing and validation.	
17.2	T17.2	Case- and ontology-based retrieval service testing and validation.	
17.3	T17.3	Beta Prototype of KDD & Simulation Platform testing and validation.	
17.4	T17.3	Final Prototype of KDD & Simulation Platform testing and validation.	

Measurement		
Objective N°	**Measurement Process and units**	
17.1	1 - The MD-Paedigree Alfa and Beta Prototypes and the final platform developed under WP 14 (derived from D 14.2, D 14.3 and D 14.4) have not been fully tested and validated. 3 - The MD-Paedigree Alfa and Beta Prototypes and the final platform developed under WP 14 (derived from D 14.2, D 14.3 and D 14.4) have been adequately tested and validated. 5 - The MD-Paedigree Alfa and Beta Prototypes and the final platform developed under WP 14 (derived from D 14.2, D 14.3 and D 14.4) have been fully tested and validated in a timely and efficient manner.	
17.2	1 - The Case- and ontology-based retrieval service developed under WP 15 (relate to D 15.1) has not been adequately tested and validated. 3 - The Case- and ontology-based retrieval service developed under WP 15 (relate to D 15.1) has been adequately tested and validated. 5 - The Case- and ontology-based retrieval service developed under WP 15 (relate to D 15.1) has been fully tested and validated in a timely and efficient manner.	
17.3	1- The Beta Prototype of the KDD & Simulation Platform developed under WP 16 (relate to D 16.2) has not been adequately tested and validated. 3 - The Beta Prototype of the KDD & Simulation Platform developed under WP 16 (relate to D 16.2) has been adequately tested and validated. 5 - The Beta Prototype of the KDD & Simulation Platform (relate to D 16.2) developed under WP 16 has been fully tested and validated in a timely and efficient manner.	
17.4	1 - The final release of the KDD & Simulation Platform (related to D 16.3) to the public has not been adequately tested and validated. 3 - The final release of the KDD & Simulation Platform (related to D 16.3) to the public has been adequately tested and validated. 5 - The final release of the KDD & Simulation Platform to the public (related to D 16.3) has been fully tested and validated in a timely and efficient manner.	

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable)**
17.1	5	3
17.2	5	3
17.3	5	3
17.4	5	3

A4- WP18 Dissemination & Training			
Lead Partner:	**LYNKEUS**	**WP Leader**:	Edwin Morley-Fletcher
Objective N°	**Task**	**Objectives' Description**	
18.1	T18.1	Project's Website implementation	
18.2	T18.2	Preparation of first dissemination materials	
18.3	T18.3	Organisation of training seminars	
18.4	T18.4	Partecipation to relevant Seminars, Workshops, Concertation Activities with Other ICT Funded Projects	
18.5	T18.4	Organisation of Scenario analysis session	
18.6	T18.5	Newsletters' preparation	
18.7	T18.6	Work of liaison, cooperation and feedback with the scientific community	
18.8	T18.7	Parent and Patient Associations Engagement	

Measurement	
Objective N°	**Measurement Process and units**
18.1	Availability of the Website.
18.2	Number of published dissemination materials.
18.3	Attendance to the training seminars.
18.4	Percentage of participating actions on possible opportunities.
18.5	Number of attendants to scenario analysis session organised.
18.6	Timely publication of the semestral newsletters.
18.7	Number of contacts with the scientific community.
18.8	Number of patient and parent associations engaged.

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result's maximum expectation)**	**Lower limits (below which result not acceptable)**
18.1	100 single users' access within month 12	75 single users' access within month 12
18.2	4 different dissemination materials produced within month 6	2 different dissemination materials produced within month 6
18.3	50	30
18.4	100%	50%
18.5	50	30
18.6	Delivered on time	+30 days
18.7	50	25
18.8	10	5

A4- WP19 Exploitation, HTA, and Medical Device Conformity			
Lead Partner:	**EMPIRICA**	**WP Leader:**	**Karl Stroetmann**
Objective N°	**Task**	**Objectives' Description**	
19.1	T19.1	Review HTA state-of-the-art and develop a set of meaningful criteria, their operationalisation and their measurement process towards analyzing (1) the facilitation of collaboraton across the relevant VPH communities by MD-Paedigree tools, services and data (2) the value-added for development acceleration of models, and for their uptake and integration into ongoing RTD work and studies. They will also be robust enough to demonstrate socio-economic benefit-cost impacts.	
19.2	T19.2	Apply the developed approach and methods towards an (1) initially formative, later (2) summative benefit-cost evaluation of MD-Paedigree infostructure. Thereby it is attempted to gauge the performance of the developing infrastrucutre tools and services with respect to benefits at both the project level and at the RTD communityl level.	
19.3	T19.3	Although the project does not aim at the direct clinical implementation level for routine services, in the longer run the real benefits for patients and society will come from such applications. Therefore a core task and objective, also proving an initial evidence base, towards a targeted and strategically aligned market exploitation of project results is to develop and preliminarily estimate benefit-cost scenario(s) for clinical impact assessment. Derived objectives are to analyse and sketch the potential impact on and benefits for • translation of models and tools developed for daily routine clinical practice, • patient safety and disease outcomes • clinical efficiency • organisational change and management • new concepts of electronic health records and patient access to its data via an avatar.	
19.4	T19.4	Organisation of a Strategic Exploitation Seminar	
19.5	T19.4	Organisation of a Clinical Impact Assessment Scenario	
19.6	T19.4	Implementation of the Exploitation Plan	
19.7	T19.5	A final objective is to prepare for and support partners in eventual market access, which also requires them to fully understand medical device conformity assessment procedures, and to undertake the mandatory validation excercises. Sub-tasks are to • understand present and draft medical device directives at the European level • be able to assess whether pieces of software must be tested as medical devices • understand medical device conformity assessment procedures • take into account patient safety, interoperability and ethico-legal requirements.	

Measurement	
Objective N°	**Measurement Process and units**
19.1	Inspection of framework and approach. Set of meaningful criteria and their operationalisation focusing on socio-economic value-added for (1) the facilitation of collaboration (2) the uptake and integration into ongoing VPH RTD
19.2	Inspection of draft deliverable. Number of assessed selected benefit-cost evaluation dimensions included in (1) formative, (2) summative evaluation of MD-Paedigree infostructure.
19.3	Review and assessment of draft deliverable. Number of clinically related benefit-cost scenario(s) for which at least very preliminary estimates and results will be available. Number of assessed selected benefit-cost evaluation dimensions with relevance towards clinical impact
19.4	Number of attendants to the Strategic Exploitation Seminar
19.5	Number of attendants to Clinical Impact Assessment scenario seminar organised
19.6	Consensus reached by the Explotation Plan between partners and external stakeholders
19.7	Inspection of deliverables to tasks 19.4 & 19.5 In preparation of exploitation (task 19.5): Available report on full understand of medical device conformity assessment procedures and guidelines on how to undertake the mandatory validation excercises. Where already at the stage of imminent exploitation (task 19.4), number of available effective assessments of the conformity of the developed “medical devices” with provisions of European and national device regulations, and their integration in the respective exploitation plans.

Indicators [Upper and lower limits associated with WP objectives and measurement units]		
Objective N°	**Upper limits (result’s maximum expectation)**	**Lower limits (below which result not acceptable**)
19.1	Validated framework and approach with 10 summary criteria on value-adding socio-economic criteria	5
19.2	(1): 6 (2): 9	(1): 4 (2): 6
19.3	2 scenarios At least 2 (or altogether 10) operationalised criteria for each dimension	One scenario At least 1,5 (or altogether 8) operationalised criteria for each dimension
19.4	40	20
19.5	40	20
19.6	100% of MD-Paedigree Partners	55% of MD-Paedigree Partners
19.7	Report available; with complete and complex legal review and understanding of present and draft medical device	Report available; covering key legal medical device issues and challenges at the European level, description of procedure for assessing

	directives, full explanation and validated procedure for assessing whether pieces of software must be tested as medical devices; full guidelines on how to undertake medical device conformity assessment procedures.	whether pieces of software must be tested as medical devices; basic guidelines on how to undertake medical device conformity assessment procedures.
	For devices ready to be marketed: The conformity to all main regulations has been assessed and the results are integrated in the first exploitation plan. Minor regulatory aspects haven't yet been analysed.	For devices ready to be marketed: Only the conformity to basic crucial regulations has been assessed. The results have been only partially integrated in the first exploitation plan. Significant regulatory aspects haven't yet been addressed.