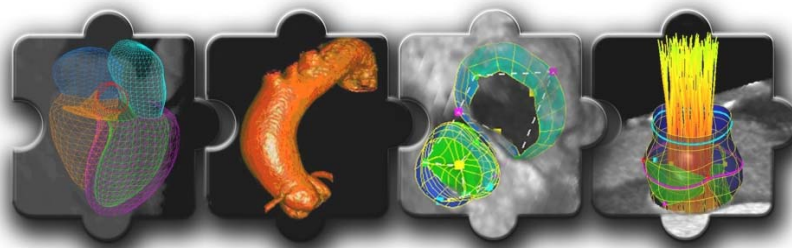


FP7-ICT-2009-4 (248421)

SeC

Sim-e-Child

<http://www.sim-e-child.org/>



Collaboration Project

Thematic Priority: ICT

Deliverable D1.4.2 Periodic Report 2

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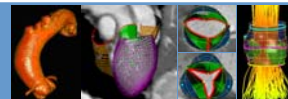
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Partner responsible for this deliverable: Siemens AG

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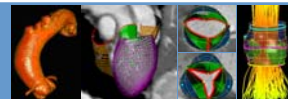
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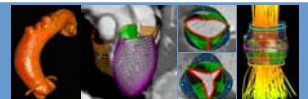
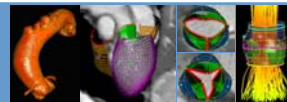


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1. Declaration by the scientific representative of the project coordinator

I, as scientific representative of the coordinator of this project and in line with the obligations as stated in Article II.2.3 of the Grant Agreement declare that:

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.
- has failed to achieve critical objectives and/or is not at all on schedule.

The public website, if applicable

- is up to date
- is not up to date

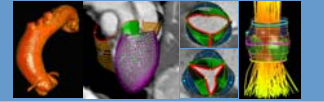
To my best knowledge, the financial statements which are being submitted as part of this report are in line with the actual work carried out and are consistent with the report on the resources used for the project (section 3.4) and if applicable with the certificate on financial statement.

All beneficiaries, 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 have been reported under section 3.2.3 (Project Management) in accordance with Article II.3.f of the Grant Agreement.

Name of scientific representative of the Coordinator: Michael Sühling

Date: 29.10.2011

Signature of scientific representative of the Coordinator: 



2. Publishable Summary

Sim-e-Child - A grid-enabled pan-Atlantic platform for large-scale simulations in paediatric cardiology

Now into its final 10 months of work the FP7 STREP Sim-e-Child (SeC) is providing a collaborative environment for multi-scale and personalized models of the growing heart and vessels including computational fluid dynamics for blood flow simulations. It operates as an extension of the Health-e-Child (HeC) grid-enabled platform and interconnects the HeC's databases with new data from US multicenter studies.

Project Description

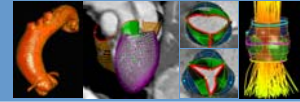
SeC started work in January 2010 as a follow-up to the FP6 HeC IP. As an early member of the Virtual Physiological Human (VPH) research community, the HeC project worked for over 4 years to build an integrated healthcare platform for paediatrics.

SeC is extending the VPH work successfully carried out by HeC in cardiology and in developing a Grid powered eHealth platform in three major ways:

1. With the support of the American College of Cardiology and Johns Hopkins, SeC is validating HeC's heart modelling capabilities using ongoing clinical US trial databases (the Coarctation Of the Aorta Stent Trial [COAST] in collaboration with the Bambino Gesù Paediatric Hospital (OPBG) in Italy.
2. The HeC models are being expanded by integrating and enhancing existing Siemens Corporate Research models of the aorta, aortic valve and mitral valve. The heart valves represent a critical component for the multiscale modeling, simulation, understanding and prediction of the whole heart function and this work represents the first data-driven modeling of the complete valvular apparatus. Furthermore the final models will include blood flow modelling and flow visualization from the Technical University of Munich. The new and comprehensive heart model will be applied to congenital aortic disease, thus enriching the portfolio of applications available on the HeC platform.
3. To support these activities, SeC is working to developing a grid-enabled platform for large scale simulations in paediatric cardiology, by integrating the HeC's Gateway and CaseReasoner (HeC's application for similarity search and decision support) with tools for simulation workflow composition and sharing of scientific experiments. This integration work is leading to the development of a collaborative environment for constructing and validating multi-scale and personalized models of a growing child's heart and vessels. Advanced clinical measurements are being derived, such as blood flow vorticity, wall shear stress, elasticity, distensibility, stiffness, and fluid structure interactions. The models in development will allow the simulation of interventions on morphology, dynamics, and haemodynamics of the aorta to make personalized predictions of optimal therapy.

Highlights of the Second Reporting Period

Clinical and Technical Work



During Reporting Period 2, SeC has begun to finalize the development of the first grid-enabled trans-Atlantic platform for large-scale simulations in paediatric cardiology and offering an online collaborative environment for the construction and validation of multi-scale personalised simulations of a growing heart and vessels. Three of SeC's areas that have advanced the most in the last reporting period are:

- SeC/HeC heart modelling capabilities have started to be validated using data from COAST by the Johns Hopkins University hospital, in collaboration with the American College of Cardiology, and on newly collected independent MR data at Johns Hopkins and Bambino Gesù hospital in Rome,
- Based on high-quality models of patient-specific geometry and dynamics, SeC's "Cardiac Hemodynamics Computation" is being used to simulate and analyze the blood hemodynamics within a child's heart and the ascending aorta and aortic arch,
- SciPort, an online facility for sharing scientific experiments, is providing users with a multi-site, Web-accessible database of SeC's paediatric cardiology data, information and knowledge for translational research and to support the definition, execution and sharing of scientific cardiac modelling and simulations.

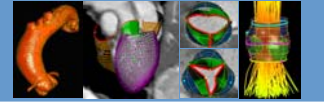
Dissemination

Over the course of the last reporting period major dissemination efforts were made by SeC at ConHIT in Berlin in April 2011 where in addition to having a high profile booth Project Coordinator Michael Suehling was a participant in the "An EU of opportunities: eHealth activities at European level and the programs of the European Commission" debate chaired by EC-Representative Loris Di Pietrantonio. Later in the year SeC was also present at the Association for European Paediatric Cardiology conference in May, the Pediatric & Adult Interventional Cardiac Symposium in Boston in July and at MICCAI in Toronto in September.

In parallel the project played a major role within the EU's VPH community and by extension was central to EU/US VPH cooperation. Specifically, Edwin Morley-Fletcher from Lynkeus was invited to coordinate the development of a summary of the success stories in EU-US collaboration on VPH research for cardiology for the *ARGOS VPH Policy Brief* which was put forward as a proposal for the extension of Memorandum of Understanding that was signed by Vice-President of the European Commission Nellie Kroes and United States Secretary of Health and Human Services Kathleen Sebelius in 2010.

Expected Results & Impacts and Preliminary Results

By the end of the final reporting period SeC hopes to have impacted on the way health knowledge is formalized, acquired, understood, represented, analysed, communicated and validated in paediatric cardiology. Thanks to the accrued investments made by the EC in the area of grid-enhanced computational capacities, it will become possible to allow large-scale patient-specific simulations utilizing computationally intensive data-driven models of the full heart and aorta with fluid dynamics and biomechanics. This capacity is based on aligned clinical databases in both the EU and the US, showing that not only the current lack of uniform clinical definitions/formats, which normally impedes electronic representation, transfer, and aggregation of much patient information, can be overcome, but also that testing new potential decision support tools can be performed on a cooperative basis across the Atlantic.



Sim-e-Child Partners:

Siemens AG (Germany)

Lynkeus (Italy)

maat France (France)

Technische Universität München (Germany)

Ospedale Paediatrico Bambino Gesù (Italy)

Siemens Corporate Research, Inc. (USA)

Johns Hopkins University (USA)

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Siemens Program and System Engineering srl (Romania)

For more information:

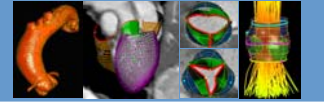
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3. Core of the report for the period: Project objectives, work progress and achievements, project management

3.1. Overall project goals

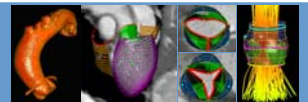
During the first two reporting periods the work advanced significantly in the following areas:

- Detailed assessment of the available clinical data by technical partners,
- Development of anatomical modelling and haemodynamics simulation software based on the given data,
- Direct involvement of clinical partners in technical development and first validation of platform and software applications.

Based on the close interaction between the technical and clinical partners, the resulting insights gained and given the vast challenges and opportunities within the wider project scope of Paediatric Cardiology simulations, the project team defined a set of five specific Validation Studies, one of which it will be feasible to achieve within the limited duration of the project. The other studies will make up the spine of future clinical exploitation activities after the end of the project. The idea is to focus on these selected areas and to provide a clear clinical benefit. Specifically, the studies plan to investigate:

- The use of patient-specific computational fluid dynamic simulations to help predict the risk of stent re-stenosis
- The usefulness of SeC software to automatically determine aortic arch geometry from MR images in the prediction of the risk of ascending aortic dilatation and aneurysm formation in bicuspid valve patients
- The use of hemodynamic modelling to understanding how stent placement could effect blood flow patterns and how the process could be used to identifying precociously patients with high-risk aortic wall complications and then improve timing of interventions
- Long-term validation efforts to assess the ability of pre-intervention MRI measures of aortic flow, wall distensibility and scar burden to predict stenting acute and medium term hemodynamic efficacy
- The long-term clinical validation of ventriculo-aortic coupling modelling the aortic valve, proximal aortic function, left ventricular mechanics coupled with blood flow to predict optimal therapeutic outcome

It is foreseen that the validation study that is performed as part of SeC and the four others will become central to SeC's exploitation work that will continue, after the conclusion of the project, to be focused around the development of a Paediatric Cardiology Digital Repository (PCDR) at OPBG. Just as HeC's work led into SeC, the expected exploitation of SeC's results is planned to build on the exploitation of HeC by focusing around adding further functionality to the PCDR, for which the first development stage is expected to be completed in H1 of 2012. The PCDR has been designed to allow for the cloud based exploitation of OPBG's paediatric cardiology data from all of its 5 sites (2 of which are in Sicily), it is thought of as a first stage realisation of what is expected to become, in the future, a Medical Information & Model Management System, a generic information technology framework for the collection, organisation, and utilisation of heterogeneous medical information, ranging from sources such as EHRs to Imaging Analytics, or even to fundamental research knowledge and information extracted from Model-Guided Medicine. As was foreseen in HeC's final exploitation plan, Maat has been the primary technological partner in building the PCDR, but in recent months current SeC partners (JHU, SCR and Siemens AG), and former HeC partner (University of Athens) have been brought into the conversation about the direction the second stage of development should take.



3.2. Project objectives for Period 2

With the aim of turning this interoperability and cooperation challenge into a concrete and focussed journey, the Sim-e-Child project partners have formalized a work plan implementing four major phases over the whole project period of 30 months. Within the first Reporting Period 1, the following two phases with corresponding objectives were in focus:

Phase 1 (Month 1 to 5) – Requirements Elicitation, Clinical Protocol and Assessment Procedures: consisted in analysing and aligning the requirements from a user and system standpoint between the EU Health-e-Child infrastructure and the US COAST database. Clinical protocols defining the criteria for the coding system, patient history, clinical findings, imaging and possibly genetics that will be used by both clinical institutions for assessing the aortic arch are established and the clinical assessment procedure for validating the heart models and their extensions were defined.

Phase 2 (Month 6 to 10) – Infrastructure Bridging and Validation of Health-e-Child models: Based on the established requirements, IT experts and physicians further defined and implemented the semantic mappings between databases. In parallel, the underlying grid infrastructure extension was prepared and deployed at JHU. The clinical validation of the Health-e-Child models took place using the US data and current Health-e-Child infrastructure and tools, based on the clinical protocol and assessment procedures as defined early in the project.

Project Period 2 focused on the Phase 3 as defined in the Description of Work:

Phase 3 (Month 11 to 20) – Interim Prototype Platform: Additional software components were integrated with the grid and extended data driven physical heart models were developed. An initial version of the simulation platform was delivered at month 15 to start the validation of the intercontinental grid with computationally intensive simulations. At month 20 the 1st version of the collaboration web portal was completed, demonstrating the underlying readiness of the infrastructure, while new VPH models started undergoing clinical assessment.

Project progress and achievements are described in detail in Section 3.3 below.

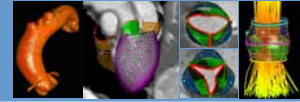
The planned Phase 4 “Extended Models and Final Clinical Assessment” will be focused on during Reporting Period 3 of the project.

3.3. Work progress and achievements during the period

3.3.1. WP1: Coordination and Project Management (WP Leader: Siemens)

WP1 ensured smooth project execution through appropriate project management. Detailed activities and work progress are described in Section 3.4 “Project Management during the Period”. The actual and planned effort person-months per beneficiary for WP1 are shown in Table 1.

WP1 Part. No.	Partic. Short Name	WP1 P1	WP1 P2	WP1 P3	WP1 Cumulative Effort Since Start	WP1 Funded Effort Whole Project	WP1 Unfunded Effort Whole Project	WP1 Total Effort Whole Project	WP1 Remaining Effort
1	Siemens	0.36	0.4		0.76	1	3	4	3.24
2	Lynkeus	2.5	1.1		3.6	4		4	0.4
4	MAAT	0	0		0		1	1	1
5	TUM	0	1		1		1	1	0
6	OPBG	0.3	0.3		0.6		1	1	0.4

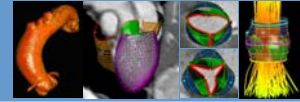


7	SCR	0.22	0.1		0.32		1	1	0.68
8	JHU	0	0.2		0.2		1	1	0.8
10	ACCF	0	0		0		1	1	1
11	PSE	0	0		0	0.5		0.5	0.5
Total		3.38	3.1	0	6.48	5.5	9	14.5	8.02

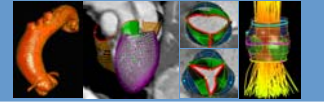
Table 1: Actual and planned effort person-months per beneficiary for WP1

According to Deliverable D1.2 "Self-Assessment Plan", the progress of WP1 is assessed as follows:

Objective No	Objective	Measurement process and units	Assessment
1	Monitoring progress of activities, efforts and expenses: timely completion of activities in each single WP.	Completion of WPs activities by deadline (in percentage)	Achieved: Completion of all WP is estimated to be 100%
2	Timely production of activity progress reports required by EU	Number days in advance/delay against delivery deadline. The 45 days delay was considered consistent with the possibility of reviewing all deliverables within the consortium.	Mostly achieved: The Periodic Reports for Period 1 and 2 were submitted within 60 days grace period. In Project Period 1, Deliverables were delivered together with the Periodic Report. This misunderstanding was corrected in Period 2 for which reports were delivered directly at the end of the reporting period.
3	Effective handling of all financial matters arising during the course of the project	Percentage of completion/update of input of financial data.	Achieved: Financial data of Project Period 1 and 2 was submitted together with Periodic Report. Corrections for Project Period 1 were submitted within 25 days.
4	Effective handling and resolution of all contractually relevant or partner conflict situations.	Percentage of solved/unsolved requests relevant to contract/Consortium Agreement amendments; percentage of solved/unsolved partners' conflicts.	Achieved: No conflicts have appeared so far.
5	Efficient organising, planning and reporting on all meetings envisioned in the project plan, and providing the project communication infrastructure	Efficient organising, planning and reporting on all meetings	Achieved: Regular telephone conferences were held between the managing partners during the reporting period with more inclusive conference calls organised when necessary. Following all conference calls action items were circulated as deemed necessary.



6	<p>Recruiting of independent experts from institutions internal and external to the consortium members to staff the Scientific Committee and the Ethical and Legal Review Committees</p>	<p>Number of experts to cover the clinical and technical areas of the project</p>	<p>Achieved:</p> <ul style="list-style-type: none"> - Dr. Dorin Comaniciu, Global Technology Field Lead at Siemens Corporate Research, ensures a high-level state-of-the-art scientific advice and oversees all technological developments undertaken by Sim-e-Child. - Dr. Gerard Martin, Chief of Cardiology at Children’s National Medical Center in Washington, DC, oversees all ethical and legal aspects of the project. - Dr. Giacomo Pongiglione, Director Department of Pediatric Cardiology and Cardiac Surgery, Ospedale Pediatrico Bambino Gesù, Rome, oversees and advices on all clinically-related activities such as clinical validation and model assessment studies.
7	<p>Prompt participation to meetings, contribution to common plans and actions as well as participation to events organised by the European Commission in case of clustering activities with other relevant EC-funded projects are organised.</p>	<p>Percentage of participating actions on possible opportunities</p>	<p>During the reporting period the SeC partners played proactive roles within the VPH NoE, the VPH-I (where Giacomo Pongiglione of OPBG is now a board member) and within ARGOS for which SeC was invited to coordinate the development of a section describing the success stories in EU-US collaboration on VPH research for cardiology of the ARGOS VPH Policy brief.</p>
8	<p>Identification, assessment, and prioritization of potential risks with the aim of minimizing, monitoring, and controlling the probability and/or the impact of unfortunate events</p>	<p>Number of potential risks identified and related actions taken</p>	<p>Achieved: no major risks have occurred so far. Potential impacts on JHU’s IT infrastructure by installing a Grid node as originally planned were evaluated. Based on this, the project partners decided to rent external Cloud resources to mitigate the risk.</p>



3.3.2. WP2: Interoperability Requirements Analysis (WP Leader: Siemens)

The objective of this work package is to establish a common understanding between the end-users and IT experts in the tasks which have to be carried out during the project's duration. In particular the tasks and achievements were:

T2.1. Requirements Elicitation and Conceptualization (Month 1-5) and T2.2. Requirements Documentation (Month 3-10)

The concepts, models and data formats to be used during the project were worked out between technical and clinical partners during several brainstorming and analysis activities during Project Period 1 and documented in Deliverable D2.1 "Initial Interoperability Requirements Analysis Document".

The clinical requirements for the assessment and validation of the anatomical models and blood flow simulations have been discussed among the clinical partners P6 OPBG, P8 JHU and P10 ACCF and have been documented in WP3.

T2.3. Requirements Revision (Month 16-20)

During Reporting Period P2, WP2's objective was to compare the projected requirements in D2.1 with the actual implementation of the Sim-e-Child platform and align the possible mismatches. The revised version of the formalized requirements (D2.2) defined the collaboration platform and resulting models due to be delivered in their final version. The outlined tasks had been completed, in particular:

- Availability of collaboration forum (see Figure 1)
- Revised Sim-e-Child platform architecture
- Integration of fluid dynamics into aorta and carotid artery models
- Definition of aorta simulation workflow and corresponding SimSys UI
- Revised data and computation network interfaces

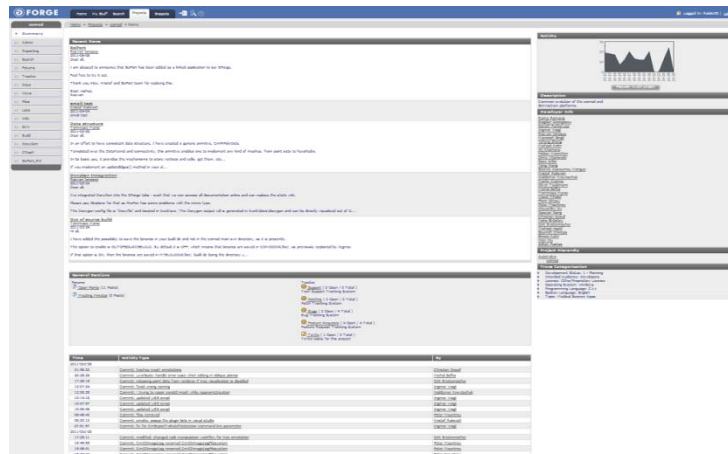


Figure 1: Collaborative forum where the project communities can interact

In order to foster the collaboration of technical partners and comply with WP2 objectives P1 Siemens and P7 SCR utilised an internal forum available to consortium members for interaction and brainstorming on the issues associated with the work plan. The forum provides additional issue tracking and general documentation framework. The forum proved to be a valuable asset, as many project partners found it directly useful.

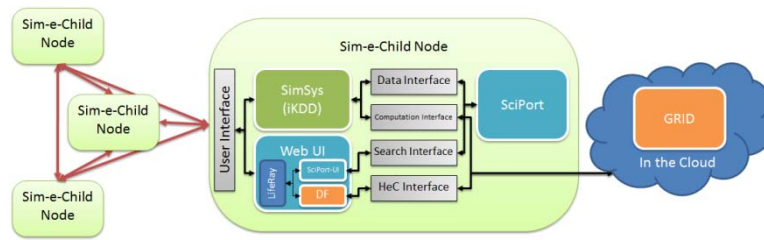
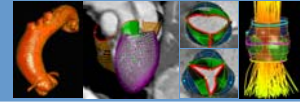


Figure 2: Revised Sim-e-Child platform component overview

In deliverable D2.2 P1 SIEMENS, P4 MAAT, P5 TUM and P7 SCR revised the overall architecture of SeC's nodes. As a result of recent trends and potential impacts to JHU's IT infrastructure in case of an on-site Grid node installation, the most suitable option to allocate computing resources is to utilize the Cloud (Figure 2). This change comes with the benefit of demand driven availability of high-performance simulation Grid.



Figure 3: Model of aorta and carotid arteries for fluid dynamics simulations

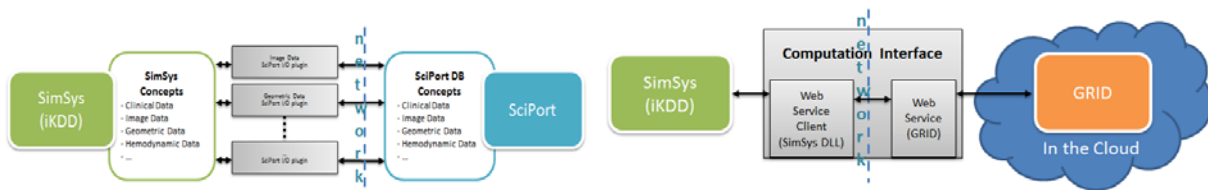
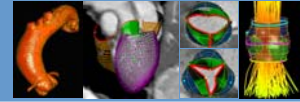


Figure 4: Revised SeC network interfaces for data and remote computation

As presented in D2.2, the integration of fluid dynamics into aorta and carotid artery at the model level was successfully completed. This milestone allowed for the further definition of aorta simulation workflow and corresponding SimSys UI by P1 SIEMENS, P5 TUM and P7 SCR (See Figure 3). As the actual Grid and SciPort infrastructures matured during Reporting Period 2, P1 SIEMENS and P7 SCR proposed improvements to allow SimSys to directly communicate with the SciPort remote databases and the up- and downloading of anatomical models and image data was streamlined. Further P1 SIEMENS and P4 MAAT crystallized the computation interface based on their mutual feedback as a slim web service interface. The necessary software plugins were finalized for both the Grid and SimSys sides and documented in D2.2 (see Figure 4).

Use of Resources and Deviations between Actual and Planned Person-Months

As planned, requirements were updated. Overall, the T2.3 has been completed during Reporting Period 2 as previously outlined. The updated Deliverable D2.2 "Revised Interoperability Requirements Analysis Document" replaces its predecessor D2.1. WP2 had fulfilled all objectives defined in D1.2



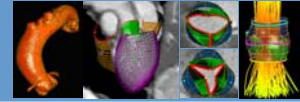
“Self-Assessment Plan”, thus the operative work in WP2 is effectively finalized and approaching its conclusion, as planned. As a large number clinical validation experiments will be carried out during Project Period 3, remaining unused efforts in this WP are likely to be needed to implement potential adjustments of requirements that may appear during this phase (especially on the clinical partners’ side).

WP2 Part. No.	Partic. Short Name	WP2 P1	WP2 P2	WP2 P3	WP2 Cumulative Effort Since Start	WP2 Funded Effort Whole Project	WP2 Unfunded Effort Whole Project	WP2 Total Effort Whole Project	WP2 Remaining Effort
1	Siemens	0.2	1.5		1.7	2		2	0.3
2	Lynkeus	0	0		0			0	0
4	MAAT	2	1		3	3		3	0
5	TUM	0	1		1	1		1	0
6	OPBG	0	0		0	2		2	2
7	SCR	0.5	0.75		1.25	2		2	0.75
8	JHU	0	0.5		0.5		2	2	1.5
10	ACCF	0	0		0	3		3	3
11	PSE	0	0		0			0	0
Total		2.7	4.75	0	7.45	13	2	15	7.55

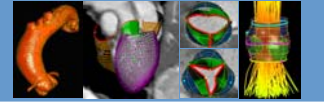
Table 2: Actual and planned effort person-months per beneficiary for WP2

According to Deliverable D1.2 "Self-Assessment Plan", the progress of WP2 is assessed as follows:

Objective No	Objective	Measurement process and units	Assessment
1	Organize two requirements analysis brainstorming meetings at end-users	Number of brainstorming meetings	Achieved: In Project Period 2, two meetings at clinical sites (May 2-3 at OPBG and July 21 at JHU) took place to discuss among other topics the clinical requirements.
2	Establish a common language and set of models among users, developers and the system deployment teams, to abstract and represent the elicited requirements in the established conceptual framework and to prioritize the interoperability/integration requirements	D2.1 establishes the requirements in such a way that they can guide subsequent developments	Achieved: Deliverable D2.1 was worked out according to the project plan to clearly guide the development to satisfy the requirements.



3	To revise/compare the requirements against delivered platform at the end of month 20.	Percentage of requirements (for the full duration of the project) fulfilled at the end of month 20	Achieved: Deliverable D2.2 was worked out according to the project plan to take into account needs for changes during the first project period such as the rental of Cloud resources.
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3.3.3. WP3: Clinical Protocol and Data Alignment, Ethical Clearance and Monitoring (WP Leader OPBG)

During the reporting period the clinical partners P6 OPBG, P8 JHU and P10 ACC finalised and defined their requirements for the clinical assessment and validation of heart models and simulated hemodynamics. The specific tasks and work progress within WP3 in Reporting Period 2 are as follows:

T3.1. Clinical Protocols Alignment (Month 11-20)

The clinical protocols to be used in Sim-e-Child were finalised by Allen Everett (JHU), Giacomo Pongiglione (OPBG) and Gerard Martin (ACC) with Siemens and MAAT in the first reporting period. It was decided that the existing protocols for COAST and Health-e-Child were to be reused for SeC. In the second reporting period, new data on patients with aortic arch disease has been and will continue to be acquired at P6 OPBG, using their clinical instrumental protocol. However, many commonalities and alignments between OPBG and COAST protocols have been documented, as reported already in D3.1 Aligned Clinical Protocols and Assessment Report. As a result, the collected data from COAST and OPBG is being integrated into a single database.

T3.2. Clinical Assessment Procedures and Documentation (Month 11-20)

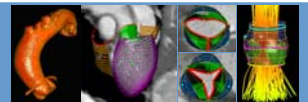
The clinical assessment work has continued to validate the quantitative measurements derived from the patient-specific left-heart models and hemodynamics simulations. Work has been completed and defined for the left-heart chambers (left ventricle and left atrium), left-heart valves (aortic valve and mitral valve) and the aorta. The chosen approach computes the clinical parameters of interest using first the clinical gold - standard defined by the experts and then compared to the result taken from the patient-specific heart model. Subsequently, the difference (error) between the two quantities has been analysed using standard statistical tools.

The primary results include the clinical protocols used for acquiring the data utilized within SeC (T3.1) and the clinical assessment procedure for validating the patient-specific models of the heart and aorta (T3.2) have been documented in Deliverable D3.1 "Aligned Clinical Protocol and Assessment Report". Additionally, within the last reporting period SeC has been validating a 3D aortic arch model from CMR images, comparing manual with model-based derived aortic arch measurements.

T3.3. Data Model Analysis (Month 11-20)

SeC utilises a database of anonymized cases with medical images in specific formats and relevant clinical parameters. Such a database allows for the development of models and simulations and their interpretation and validation thereof by clinicians. During the last reporting period the data has continued to be collected by partners in the EU (OPBG) and the US (JHU and their partners in clinical trials and registries).

The cardiology data from the HeC project was extracted from the databases for right ventricular overload (RVO) which contains the Tetralogy of Fallot (ToF) cases relevant for Sim-e-Child. The clinical Meta data from the COAST trial was provided by JHU as PDF forms and spread sheets with a data export from the database. The clinical data from OPBG were extracted directly from the Hospital and Radiology Information Systems (RIS) and from the PACS in the form of Word documents and DICOM images together with clinician notes and clinical parameters. Data formats of the different sources at P6 OPBG, P8 JHU and existing HeC data have been analysed and compared in detail. Accordingly, semantic mappings between data structures were specified and have been implemented. The mapping and integration of the data from different sites and sources is described in Deliverable D3.2 "Data Model Mapping Report".



During the analysis of existing clinical databases (COAST, GenTAC, HeC), it turned out that a large part of the image data was not suitable for 3D cardio-vascular anatomical modelling. The major part of the data was acquired using 2D imaging protocols. However, realistic and clinically meaningful haemodynamic simulations can only be performed based on 3D models. The GenTAC data, in particular, does not contain image data that is useful for the intended use. GenTAC imaging is acquired with a mixture of CT and MRI with no standard protocol and from multiple institutions. As corrective action, P8 JHU has submitted an amendment to the existing HeC IRB protocol to allow retrieving data on patients with aortic aneurysms. Once the IRB amendment was approved by the ethics commission, additional data was collected for Sim-e-Child.

Data acquisition at P6 OPBG continued throughout the second reporting period with approximately two new patients per week. At the present, 92 patients with aortic arch disease have been collected from OPBG. OPBG has collected two CMR 3D sequences for each patient, CE-MRA and free-breathing ECG-gating 3D SSFP, acquired in an average of cardiac cycle and in diastole respectively. These two sequences have facilitated the construction of the 3D aortic arch model. The number of patient examinations at OPBG has been helped by the installation of a new MRI machine.

P8 JHU, with approval of the expanded HeC IRB protocol, has identified 71 MRI and 56 CT cases with coarctation, most of which will be adequate for modeling. In addition, JHU has modified their protocol in the cardiac MR suite to include flow acquisition for validation purposes.

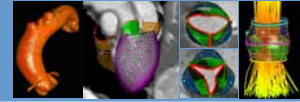
T3.4. Ethical Clearance and Monitoring (Month 1-30)

Both P6 OPBG and P8 JHU received all the necessary ethical clearance and all new participating patients at OPBG have signed the informed consent forms.

Use of Resources and Deviations between Actual and Planned Person-Months

The actual and planned effort person-months per beneficiary for WP3 are shown in Table 3. The efforts spent mainly match the original planning. Efforts at JHU were not formally accounted but estimated since JHU is an unfunded partner. ACCF mainly supported the work by consulting the team with clinical insights by Dr. Gerard Martin. These actual efforts were not formally accounted. Parts of ACCF's unused funding is planned to be re-assigned to fund additional data collection driven by JHU to collect pre-interventional MRI data which is not part of the COAST trial (data collection is already ongoing). Such data is crucial for the clinical validation of the developed models. A corresponding amendment request was sent to the Project Officer in May 2011 and is currently being processed.

WP3 Part. No.	Partic. Short Name	WP3 P1	WP3 P2	WP3 P3	WP3 Cumulative Effort Since Start	WP3 Funded Effort Whole Project	WP3 Unfunded Effort Whole Project	WP3 Total Effort Whole Project	WP3 Remaining Effort
1	Siemens	0.2	2.5		2.7	3		3	0.3
2	Lynkeus	0	0		0			0	0
4	MAAT	2	0		2	2		2	0
5	TUM	0	0		0			0	0
6	OPBG	15	1		16	16		16	0
7	SCR	1.2	0		1.2	1		1	-0.2
8	JHU	0.5	2		2.5		16	16	13.5
10	ACCF	0	0		0	12		12	12



11	PSE	0	0		0			0	0
Total		18.9	5.5	0	24.4	34	16	50	25.6

Table 3: Actual and planned effort person-months per beneficiary for WP3

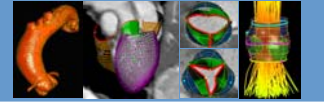
According to Deliverable D1.2 "Self-Assessment Plan" the progress of WP3 is assessed as follows:

Objective No	Objective	Measurement process and units	Assessment
1	To make JHU local and clinical trial databases interoperable with Sim-e-Child platform. To define and document semantic mappings between Sim-e-Child and JHU clinical trial databases as needed by WP4.	Degree of DB and data model interoperability	90% of JHU's and OPBG's data has now been integrated into a single data base and included on the SeC platform.
2	To establish a consensus on the clinical protocol and corresponding data schemata alignment for studying extended heart models and their application to congenital aortic disease.	Availability of agreed clinical protocols	The data protocol commonalities between aortic coarctation and thoracic aneurysm protocol have been assessed. In addition the commonalities and alignment between OPBG and COAST protocols have been documented. Because they are quite similar, the COAST and OPBG data have been integrated into a single database.
3	To gain ethical approval at the clinical institutions and provide guidance to technical partners in all concerned work packages.	Number of participating hospitals with ethical approval	Ethical approval at the clinical institutions has been obtained at a rate of 100%. All participants have received and consented to taking part in the study.
4	To define and document the clinical assessment procedures to be followed for the validation of resulting models in WP5.	Availability of clinical assessment procedures	The clinical assessment procedures have been defined to create and validate heart models. In the second reporting period the validation of 3D aortic arch model built from CMR images continued.

3.3.4. WP4: Simulation and Collaboration Platform Development (WP Leader MAAT)

The specific tasks and work progress within WP4 in Reporting Period P1 are as follows:

T4.1. JHU Grid Connection (Month 1-5)



The technical partners, in particular P4 MAAT and P1 Siemens, decided to externalize the US Grid node resources so to facilitate its expansion, while not impeding P8 JHU's IT department. The US Grid node resources will be subcontracted from an appropriate Cloud provider on a requirements basis as soon as clinical validation studies begin to be executed as is expected in Project Period 3. For the moment, the bandwidth of the European Grid node is high enough to be used from the US.

T4.2. Case Databases Connection (Month 6-10)

Completed in reporting period one: See D1.4.1

T4.3. Simulation Data Management (Month 1-5)

Completed in reporting period one: See D1.4.1

T4.4. Simulation Environment Gridification (Month 6-10)

The platform developed within Project Period 1 was extended to completely interconnect SimSys/iKDD, SciPort and GRID systems. In addition, SciPort and the Simulation Platform are available online from the SeC portal: <http://sec-portal.maatg.fr/group/simechild/project-home> (Figure 5).

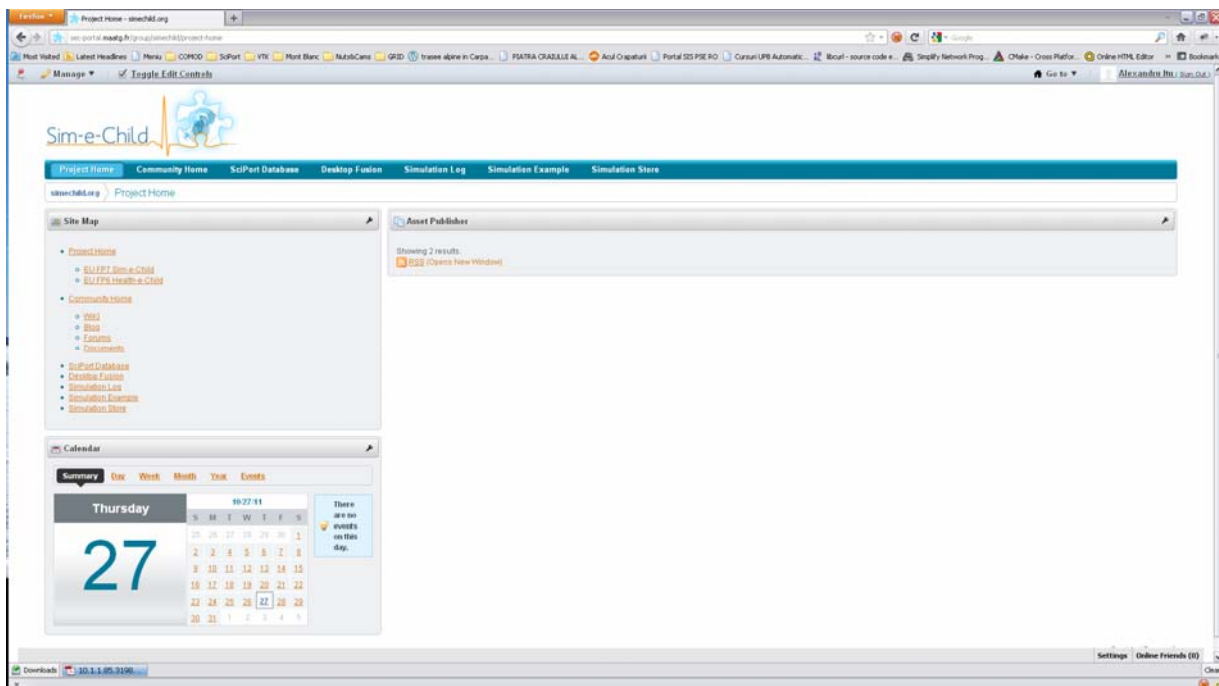


Figure 5: Sim-e-Child portal

Form SimSys/iKDD jobs can be submitted to run on the GRID. Their status can be monitored in the Web Portal and the results can be retrieved once the jobs have finished. The connection of SimSys and GRID is realized through secured web services (Figure 6).

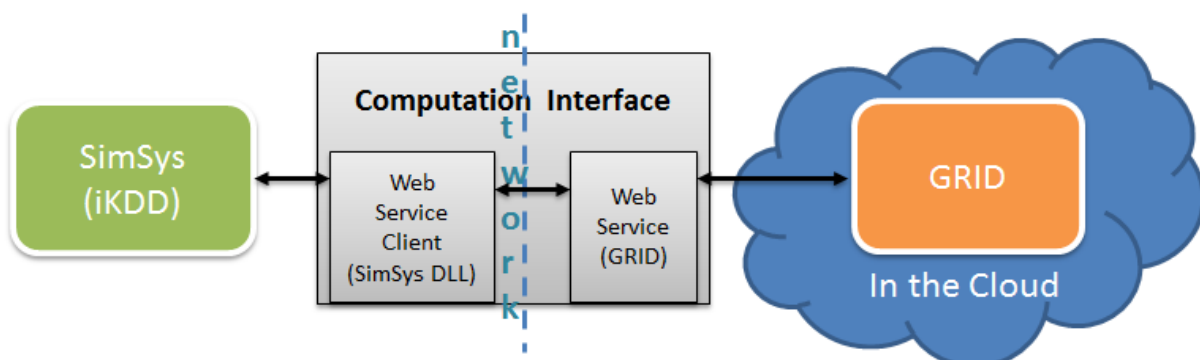


Figure 6: SimSys and the Grid infrastructure are connected by secured web services

The web service client is implemented in the form of a DLL plugin, which contains directly generated C++ stub code from the WSDL web service description. The DLL is linked and accessed directly, during runtime from the SimSys component. The monitoring notifications use a callback mechanism to notify the SimSys component when new events/results are available.

T4.5. Simulation and Collaboration Platform Development (Month 1-30)

During this reporting period, the SeC simulation platform was extended with additional components. In addition, extensive testing was performed to make the platform more stable and to remove identified bugs. In particular, P11 PSE focused on implementing the following features:

- Single-Sign-On functionality using CAS server was added to SciPort to integrate it with other systems.
- RESTful services with JSON was implemented in order to expose all functionality not only through the web GUI but also through the REST API.
- User manuals were written to document all functionalities from the web GUI and also all available RESTful API.

T4.6. Platform Integration and Testing (Month 7-30)

A development test-bed has been setup and provided by MAAT, which allows technical partners to exercise and test their respective platform components, as well as their integration within the SeC infrastructure and simulation platform.

During this reporting period, the development test-bed was really useful for the SimSys/iKDD integration with the Grid API.

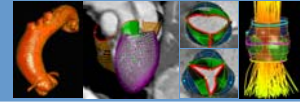
P11 PSE has implemented a series of unit and integration tests which covers the GRID and Sciport integration. In addition to the unit tests for the web-services and for Sciport, an automated build and testing framework has been set up using cDash.

T4.7. Sim-e-Child Platform Maintenance and Access Provision (Month 1-30)

The SeC Simulation and Collaboration Platform as well as underlying Grid infrastructure were appropriately maintained over the period, since their respective deployment. Updates of the different components have been completed both at the grid middleware level and at the Gateway services one.

T4.8. Health-e-Child Platform Maintenance (Month 5-30)

The Health-e-Child sites which were previously migrated have been updated and maintained during the second reporting period.



Use of Resources and Deviations between Actual and Planned Person-Months

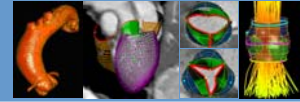
The actual and planned effort person-months per beneficiary for WP4 are shown in Table 4. Actual efforts are considered to be mainly in alignment with the planning. Remaining efforts at the clinical sites will be needed to conduct the clinical validation studies which are in focus during the last period of the project.

WP4 Part. No.	Partic. Short Name	WP4 P1	WP4 P2	WP4 P3	WP4 Cumulative Effort Since Start	WP4 Funded Effort Whole Project	WP4 Unfunded Effort Whole Project	WP4 Total Effort Whole Project	WP4 Remaining Effort
1	Siemens	0.2	1		1.2	2		2	0.8
2	Lynkeus	0	0		0			0	0
4	MAAT	6	6		12	14		14	2
5	TUM	0	0		0			0	0
6	OPBG	0	0		0	2		2	2
7	SCR	1.5	0.7		2.2	2.75		2.75	0.55
8	JHU	0.5	0.25		0.75		2	2	1.25
10	ACCF	0	0		0	6		6	6
11	PSE	5	8.5		13.5	17		17	3.5
Total		13.2	16.45	0	29.65	43.75	2	45.75	16.1

Table 4: Actual and planned effort person-months per beneficiary for WP4

According to Deliverable D1.2 "Self-Assessment Plan", the progress of WP4 is assessed as follows:

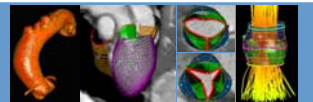
Objective No	Objective	Measurement process and units	Assessment
1	To prepare the grid deployment logistic, by issuing a set of hardware and software specifications for purchase and installation.	Availability of hardware and software specifications	Achieved: In "D4.1 Grid and Databases Connection Report", a complete specification of the hardware that is/will be deployed has been provided. This includes configuration samples for cloud providers and a description of the infrastructure deployed in Europe (central node + site).
2	To setup the hardware and deploy the grid software to connect remote US partners to the current Health-e-Child infrastructure in EU and to test the interconnection between US and EU	Number of deployed and connected grid nodes in the US	D4.1 provides a complete description of the US grid node. The cloud provider bandwidth is very good and therefore a high quality of services will be provided.



	according to requirements as specified in WP2.		
3	To make US case databases interoperable with Health-e-Child databases using the data integration tools of Health-e-Child.	Percentage of migrated CRFs allowing (semi-)automatic migration of patient data	Existing data in COAST and GenTAC data bases were reviewed. As reported in D.1.4.1, GenTAC data turned out not to be useful for the specific requirements of the project. Instead, JHU successfully filed an IRB approval to collect appropriate data. All suitable COAST cases were migrated to the SeC database. In addition, pre-interventional data is being collected by P8 JHU to further extend the data base. Tetralogy of Fallot cases from the HeC database were also migrated and used for model validation as described in D5.1.
4	To gridify and integrate within the Health-e-Child Gateway the enabling scientific workflow design and management facilities.	Modelling/Simulation experiments can be executed on SeC platform	Achieved: First modelling and simulation experiments have been executed and documented in WP5.
5	To package, test and roll out new versions of the resulting Sim-e-Child platform software	Effort required to package, test and roll out new versions of the Sim-e-Child platform	Since a few weeks, all the deployments are managed by the Puppet software (http://puppetlabs.com/). Puppet, an automated administrative engine for your *nix systems, performs administrative tasks (such as adding users, installing packages, and updating server configurations) based on a centralized specification. Thanks to it, deployment of new sites or updates can be done quite quickly and semi-automatically
6	To set up and maintain an appropriate project communication infrastructure, including website and document repository	Availability of website and document repository	Achieved: The SeC platform is deployed and properly maintained. It provides many tools such as a documents library and a Wiki to allow an appropriate project communication.



7	To respect the ethical requirements as specified by and advised in WP3	Number of violations	Achieved: No violations have been encountered so far.
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3.3.5. WP5: Development and Assessment of Personalized Child Heart Models (WP Leader SCR)

The specific tasks and work progress within WP5 in Reporting Period P1 are as follows:

T5.1 Validation of Health-e-Child LV and RV Models (Month 1-10)

Completed in the first reporting period: See D1.4.1

T5.2 Extension of the Health-e-Child Model with Aorta, Aortic Valve and Mitral Valve (Month 1-10)

As outlined in the previous Periodic Report D1.4.1, this task was extended to Project Period 2. The objective within this work item is to enhance the HeC cardiac models with anatomical models for the aorta, aortic valve, and mitral valve. The main work focus of P1 Siemens and P7 SCR within Reporting Period 2 was on extending the aortic model with the carotid arteries (Figure 7), the mitral valve with the subvalvular apparatus (Figure 9) and experimenting with different MRI acquisition protocols to find the best trade-off between MRI image acquisition time and mitral valve model estimation error (Figure 8). P1 Siemens and P7 SCR have developed hierarchical machine-learning algorithms for patient-specific fully-automatic model estimation of the complete aortic model (aortic root ascending aorta, aortic arch, supraaortic arteries and descending aorta). Within Period 2 the developed algorithms in Period 1 were extended from “semi-automatic” to “fully-automatic” complete aortic model estimation. The developed algorithm was applied on 212 3D MRI volumes provided by JHU and OPBG and produced a patient-specific complete aortic model without a single failure. This work will be submitted in a form of a technical paper at the International Symposium on Biomedical Imaging, Barcelona, Spain 2-5 May 2012.

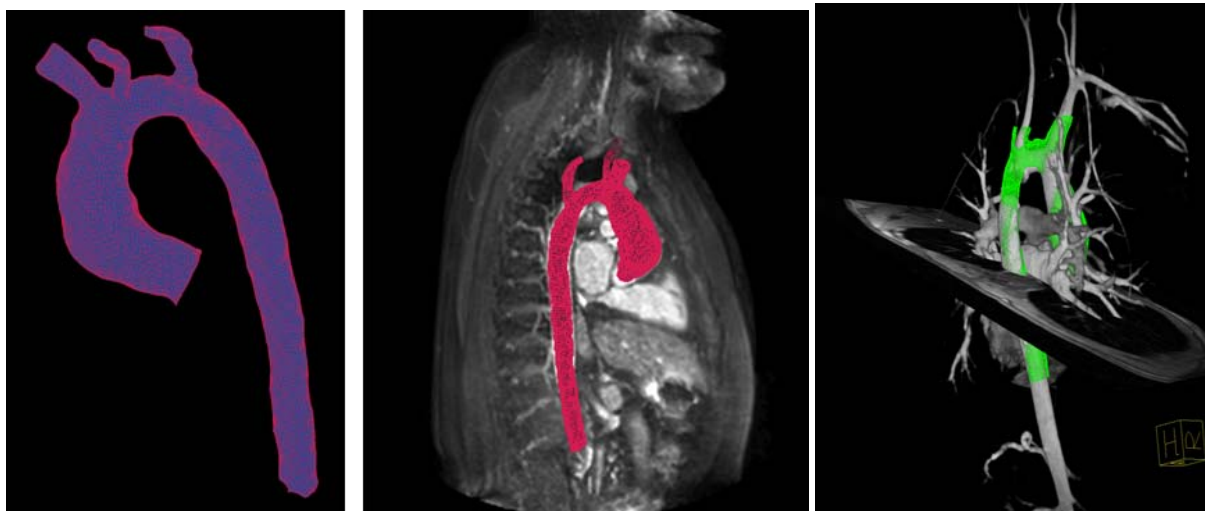


Figure 7: Aortic model extended with supraaortic arteries

To enable accurate and robust cardiac valve modelling, P1 Siemens has experimented with existing MRI protocols Siemens-internally by adapting them to optimize mitral valve model estimation. Acquisition protocol of six parallel slices perpendicular oriented between the mitral valve commissures (Figure 8) results in the best trade-off between reduced acquisition time and model estimation error.

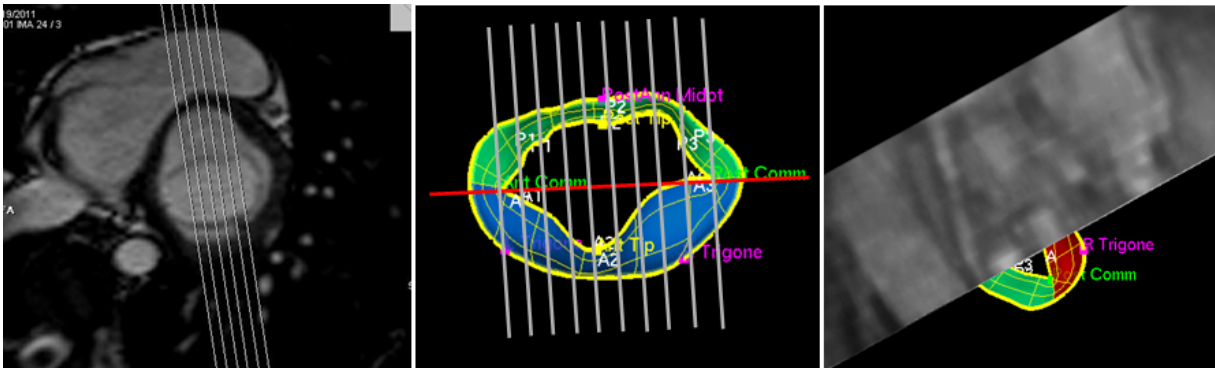
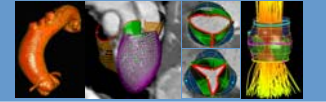


Figure 8: MRI Acquisition Protocol

Based on the developed MRI protocol, a novel regression-based learning algorithm was introduced by P1 Siemens for patient-specific 3D+t mitral valve model estimation. Furthermore, the proposed mitral valve model was extended with subvalvular structures (posterior and anterior papillary head and chordae tendineae). Dynamic model-based measurements (distance between landmarks, valve areas etc.) can be automatically derived from the model [Vitanovski et al. 2011].

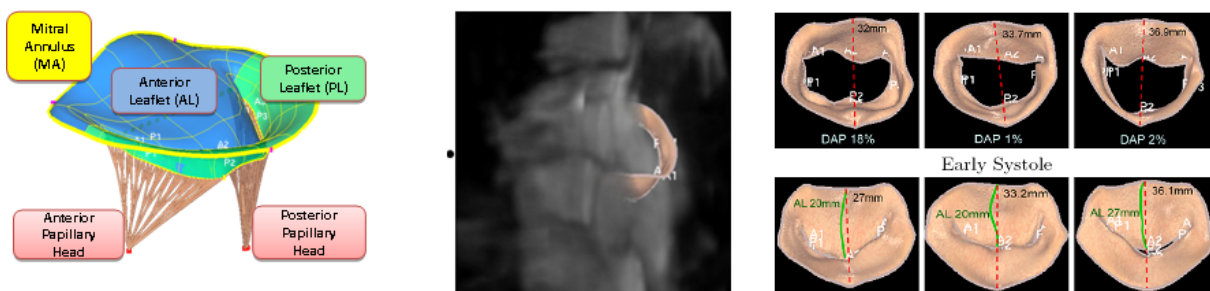


Figure 9: Left. Mitral Valve model extended with subvalvular structures. Middle. MV model fitted into MRI data. Right. Automatically derived model-base MV measurements

T5.3 Extension of the Heart Models with Physical Constraints (Month 6-20)

P7 SCR developed and performed first computational fluid dynamics (CFD) blood-flow simulations from the integrated heart model estimated from CT data as already described in D.1.4.1. The main focus of P7 SCR within Reporting Period 2 was on performing CFD blood-flow simulations for the complete aortic model (Figure 7) and extending the developed machine-learning algorithms for mitral valve model estimation with biomechanical constraints. P7 SCR has developed a novel discriminative learning technique that is constrained by a biomechanical model of the MV leaflets (Figure 10). The model is automatically initialized in the images and local minima are avoided through incremental search and discriminative learning. The biomechanical constraint is ensured by solving a dynamic system between time frames [Voigt et al. 2011].

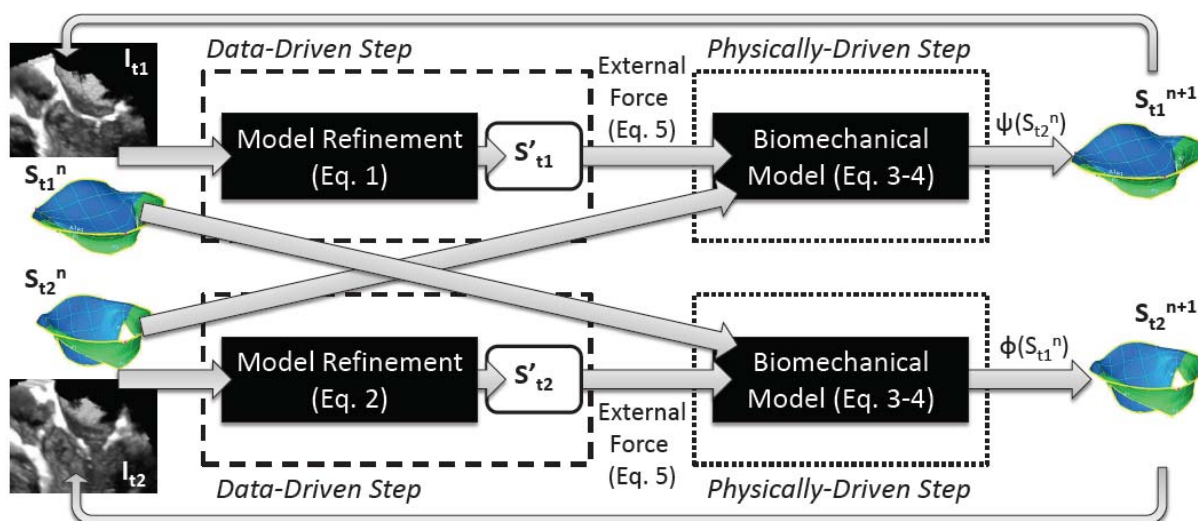
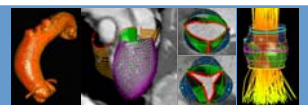


Figure 10: Proposed framework for physically-constrained mitral valve estimation

T5.4 Evaluation of Models for Congenital Aortic Arch Disease (Month 15-30)

Within the Reporting Period 2 P7 SCR together with P6 OPBG and P8 JHU evaluated the accuracy of the complete aortic model by comparing manual measurements of the min and max diameter of the aorta at five different regions (aortic sinus, sino-tubular junction, ascending aorta, transvers arch, descending aorta) with automatically derived one. Mean measurement error of 1.59 ± 0.6 mm was achieved for the min diameter and 1.44 ± 0.9 mm for the max diameter.

T5.5 Simulation Experiments (Month 15-30)

The main focus of P1 Siemens, P7 SCR and P5 TUM within Period 2 was to setup the whole simulation pipeline starting from image analytics, boundary conditions, model estimation, and up to CFD blood-flow simulation (Figure 11). Furthermore, P5 TUM developed algorithms for flow rate simulation from PC-MRI images. The flow rate is then used as a boundary condition in the CFD blood-flow simulation. In ongoing work the CFD blood-flow simulation will be evaluated on available patients with pre- and post op data.

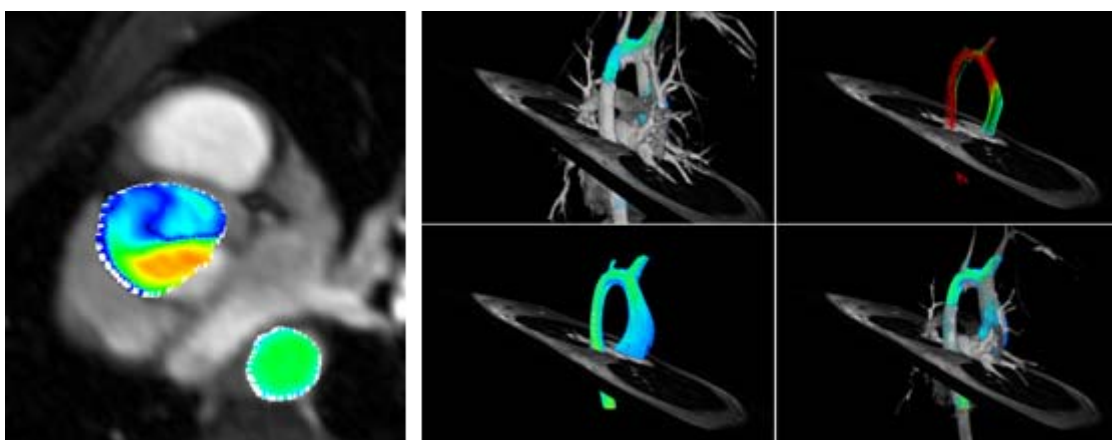
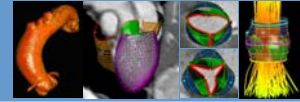


Figure 11: CFD blood-flow simulation pipeline

Use of Resources and Deviations between Actual and Planned Person-Months



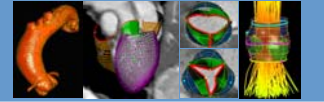
The actual and planned effort person-months per beneficiary for WP5 are shown in Table 5. Overall, the development of the comprehensive modelling and simulation engine progressed well, reflected by the actual efforts of the technical project partners that match the planned efforts quite well. First clinical simulation results were obtained already and the remaining efforts of the clinical partners will be spent during Project Period 3 to carry out clinical validation studies as planned.

WP5 Part. No.	Partic. Short Name	WP5 P1	WP5 P2	WP5 P3	WP5 Cumulative Effort Since Start	WP5 Funded Effort Whole Project	WP5 Unfunded Effort Whole Project	WP5 Total Effort Whole Project	WP5 Remaining Effort
1	Siemens	0.46	4.8		5.26	7		7	1.74
2	Lynkeus	0	0		0			0	0
4	MAAT	0	1		1	1		1	0
5	TUM	1	15		16	14		14	-2
6	OPBG	0	16		16	32		32	16
7	SCR	1.5	2.6		4.1	7		7	2.9
8	JHU	0	0.25		0.25		23	23	22.75
10	ACCF	0	0		0	5		5	5
11	PSE	0	0		0			0	0
Total		2.96	39.65	0	42.61	66	23	89	46.39

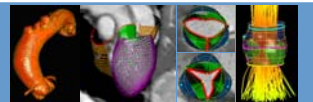
Table 5: Actual and planned effort person-months per beneficiary for WP5

According to Deliverable D1.2 "Self-Assessment Plan", the progress of WP5 is assessed as follows:

Objective No	Objective	Measurement process and units	Assessment
1	To clinically assess the Health-e-Child heart models and their extensions following the procedure and guidelines as provided by WP3.	Number of cases validated	Achieved: The heart models were trained on 114 cases and evaluated on 15 unseen patients (the target was to validate at least on 10 cases).
2	To extend the Health-e-Child personalized heart models with the aorta, aortic valve and mitral valve	Time required for the semi-automatic modelling of the left heart	Achieved: the complete aortic model is automatically estimated within 1min. The Mitral Valve model is semi-automatically estimated within 2min.
3	To extend the left heart models with computational fluid dynamics simulations on the grid-infrastructure and provide advanced	Integrated manipulation/visualization of anatomical and hemodynamical data	Achieved: See descriptions of WP4 and WP5.



	visualization of the simulation results.		
4	To build, test and evaluate the models using the simulation platform.	Number of cases evaluated	Achieved: accuracy of aortic model estimation was clinically validated on 34 patients (the number exceeds the target number of 25 cases)



3.3.6. WP6: Dissemination and Exploitation (WP Leader Lynkeus)

The SeC website (www.sim-e-child.org) went live in the first quarter of 2010 in advance of the conclusion of the HeC project (www.health-e-child.org). The website was designed to be completely compatible with the directions laid out by the EC for all dissemination materials and Annex II of the Grant Agreement. In the first reporting period the website was updated at the EC's request to include news from the High Tech Wire service.

In the second reporting period the website's functionality was expanded to include a private side which will allow SeC's partners to securely transfer large files more efficiently when there is the need to. A minor update of the website to bring it up to date with the development of the project was undertaken in March 2011 in advance of SeC's participation in the ConHIT eHealth conference in Berlin. A major update to the website was made in July 2011 to take into account the Consensus Report that came out of SeC's first Periodic Report. The Report requested that the website "make to goals of the project clearer"; this update of the website was therefore done in conjunction with this task, once the clinical partners were able to define more specifically the clinical objectives of the project. The result was a new page on the website called "SeC Validation Studies".

The studies that the new area of the website describes are examples of the goals that SeC's clinicians are pursuing. The timeframe of the project will however not allow for the completion of all of them and they have therefore been designed to evolve as clinicians gain more experience with SeC's tools. Before the end of the first quarter of 2012 the five studies will have been refined, focused and prioritised by all the relevant partners to ensure that by the end of the project, in June 2012, one at least will be completed and the remaining ones will be emblematic of SeC's potential future clinical exploitation activities after the end of the project. For the time being, the studies should therefore not be considered to be set in stone or to be indicative of work that will be necessarily carried out with EC funding and within the time limits of the project.

More information can be found on the website in "D6.2 Up dated dissemination materials" which was delivered at the beginning of month 21.

T6.2 Dissemination Materials

Only minor tweaks were made to SeC's templates and general dissemination materials. For the dissemination events that are listed in T6.3 specific slides and posters were produced to match the expected audience. More information and copies of the posters can be seen in "D6.2 Updated dissemination materials".

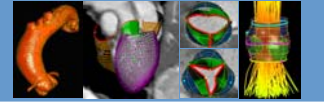
Additionally the ACC has now published a listing and description of the SeC project on their website which can be found at: www.cardiosource.org/ACC/International-Center/Where-We-Are.aspx

T6.3 Seminars, Workshops, Concertation Activities with Other ICT Funded Projects

During the second reporting period the work of SeC was disseminated at the following conferences:

conhIT (Berlin, 24-26 April 2011)

SeC was one of 241 exhibitors at the conhIT Industrial Fair, Europe's largest Healthcare IT conference that presented the full range of eHealth products and services. Along with established solutions conhIT also features quality innovations and trends in Healthcare systems. In addition to having a booth populated with posters, a power point presentations and videos of some of SeC models, SeC's Coordinator, Michael Suehling from Siemens, participated in a panel discussion on the EU's endeavours in eHealth arena. The discussion was entitled "An EU of opportunities: eHealth activities at European level and the programs of the European Commission" and chaired by EC-Representative Loris Di Pietrantonio.



The following link is to a conHIT article including a video of the panel discussion: www.healthtechwire.com/PremiumPro-Single.244+M54af3bd27ce.0.html, the video is also available through YouTube at www.youtube.com/watch?v=LkRTyNtutP0.

Pediatric & Adult Interventional Cardiac Symposium (Boston, USA, July 2011)

Giacomo Pongiglione also co-directed the Pediatric & Adult Interventional Cardiac Symposium (Pics & Aics 2011), which took place in Boston, USA, from 23rd to 27th July 2011, where SeC's clinical advances were presented in conjunction with the announcement of the Paediatric Cardiology Digital Repository the completion of which is due in the first half of 2012 at the 5 OPBG sites across Italy (more details on this development are given in section T6.6).

AEPC validation paper on Right ventricle quantification – presented in Granada, Spain, 2011
Association for European Paediatric Cardiology, 18-21 May 2011.

SeC at MICCAI 2011 (Toronto, September, 2011)

Two workshop publications at MICCAI 2011 –presented in September in Toronto

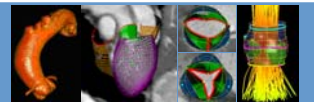
SeC was featured in a presentation given by David Manset at WHO's eHealth pavilion during the ITU Telecom World 2011 symposium, which took place in Geneva from the 24th to the 27th of October. In addition, live demonstrations were given to the pavilion visitors of the SeC simulation platform (<http://www.itu.int/ITU-D/cyb/events/2011/Telecom11/e-health/index.phtml>).

Conference Presentation List:

- International Symposium of Grid Computing in March 2010 in Taipei
- Health-e-Child Final Conference, Sestri Levante (Italy), April 2010
- GARR's First National Conference on Health Research, Cernobbio (Italy), November 2010
- ICT2010, Brussels, September 2010
- MICCAI Beijing, September, 2010
- VPH 2010, Brussels, September 2010
- Health Informatics New Zealand 2010 Conference November 2010, Wellington (New Zealand)
- 45th Annual Meeting of the Association of European Paediatric Cardiology, May 2011, Grenada (Spain),
- conHIT, Berlin (Germany), April 2011
- Pediatric & Adult Interventional Cardiac Symposium (Boston, USA, July 2011)
- Association for European Paediatric Cardiology, 18-21 May 2011.
- MICCAI 2011 (Toronto, September, 2011)
- ITU Telecom World 2011, WHO eHealth Pavilion (Geneva, 24-27 October 2011)

SeC's Final Conference

In the second reporting period the SeC partners began discussion about hosting a final conference. The final conference will be designed to disseminate the results of the SeC and involve renowned experts in the VPH field to explain their work and to assess and validate the work of SeC. The conference is planned to be held in either Brussels or Baltimore/Washington D.C. in the spring of 2012.



T6.4 Newsletter

The first SeC newsletter was published in Month 12, as was promised in the SeC's original DoW. The newsletter included sections on SeC's grid infrastructure and web portal, the heart modelling and cardiac blood flow simulation work of 2010 and highlights of the dissemination events of the first 12 months. The newsletter was distributed to interested parties, used at all dissemination and networking events and uploaded to the website. In advance of the ConHIT conference the Newsletter was updated to reflect the progress of the conference.

The first newsletter can be found at: www.sim-e-child.org/2/sec_s_first_newsletter_1502279.html

The second newsletter is scheduled to be published at the end of 2011.

Scientific journals List:

Reporting Period 1

Amodeo A, Brancaccio G, Michielon G, Filippelli S, Ricci Z, Morelli S, Gagliardi MG, Iacobelli R, Pongiglione G, Di Donato RM., [Pneumatic pulsatile ventricular assist device as a bridge to heart transplantation in pediatric patients](#), *Artif Organs*. 2010 Nov;34(11):1017-22.

Barcudi S, Sanders SP, Di Donato RM, de Zorzi A, Iacobelli R, Amodeo A, Gagliardi MG, Borgia F, Pongiglione G, Rinelli G., [Aberrant left innominate artery from the left descending aorta in right aortic arch: echocardiographic diagnosis](#), *J Am Soc Echocardiogr*. 2010 Feb;23(2):221.e5-7.

Brancaccio G, Amodeo A, Ricci Z, Morelli S, Gagliardi MG, Iacobelli R, Michielon G, Picardo S, Parisi F, Pongiglione G, Di Donato RM., [Mechanical assist device as a bridge to heart transplantation in children less than 10 kilograms](#), *Ann Thorac Surg*. 2010 Jul;90(1):58-62.

Carotti A, Albanese SB, Filippelli S, Ravà L, Guccione P, Pongiglione G, Di Donato RM., [Determinants of outcome after surgical treatment of pulmonary atresia with ventricular septal defect and major aortopulmonary collateral arteries](#), *J Thorac Cardiovasc Surg*. 2010 Nov;140(5):1092-103.

Cavallini M, Di Zazzo G, Giordano U, Pongiglione G, Dello Strologo L, Capozza N, Emma F, Matteucci MC., [Long-term cardiovascular effects of pre-transplant native kidney nephrectomy in children](#), *Pediatr Nephrol*. 2010 Dec;25(12):2523-9. Epub 2010 Sep 25.

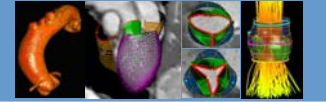
Comaniciu, D., [Patient-Specific Modelling of Whole Heart Anatomy. Dynamics and Hemodynamics from 4D cardiac CT Images](#), *Interface Focus* 2010 - (invited publication-submitted)

De Caro E, Smeraldi A, Trocchio G, Calevo M, Hanau G, Pongiglione G., [Subclinical cardiac dysfunction and exercise performance in childhood cancer survivors](#), *Pediatr Blood Cancer*. 2011 Jan;56(1):122-6.

De Caro E, Spadoni I, Crepaz R, Saitta M, Trocchio G, Calevo MG, Pongiglione G., [Stenting of aortic coarctation and exercise-induced hypertension in the young](#), *Catheter Cardiovasc Interv*. 2010 Feb 1;75 (2):256-61. Erratum in: *Catheter Cardiovasc Interv*. 2010 Jun 1;75 (7):1143.

Everett, A., Development and validation of a novel automated learning based algorithm for quantification of MRI right ventricular volume in Tetralogy of Fallot, submitted abstract for the 45th Annual Meeting of the Association of European Paediatric Cardiology, to be held in Granada, Spain in May 2011.

Gagliardi MG, Papavasileiou L, Pongiglione G, Rescue treatment by percutaneous closure of interatrial septal defect or PFO in infants with berlin heart, *Catheter Cardiovasc Interv*. 2010 Sep 17



Grbic S., Ionasec R., D. Vitanovski, Ingmar Voigt, B. Georgescu, , [N. Navab](#), D. Comaniciu, [Complete Valvular Heart Apparatus Model from 4D Cardiac CT](#), Medical Image Computing and Computer Assisted Intervention (MICCAI), Beijing, China, September 20-24 2010.

Ionasec R., Georgescu B., Navab N., Comaniciu D., [Patient-Specific Modelling of Whole Heart Anatomy, Dynamics and Hemodynamics from 4D cardiac CT Images](#), BMT – 2010, Rostock2010

Ionasec R., Suehling M., Comaniciu D., [Sim-e-Child: Grid-Enabled Platform for Simulations in Paediatric Cardiology Toward the Personalized Virtual Child Heart](#) – VPH NoE 2010

Mihalef, V., Ionasec, IR., Sharma, P., Georgescu, B., Huber, M., Comaniciu, D., [Patient-Specific Modelling of Whole Heart Anatomy, Dynamics and Hemodynamics from 4D cardiac CT Images](#), Virtual Physiological Human Conference 2010, Brussels 2010

Vitanovski D., [Razvan Ioan Ionasec](#), A. Tsymbal, B. Georgescu, M. Huber, Joachim Hornegger, D. Comaniciu, [Cross-modality Assessment and Planning for Pulmonary Trunk Treatment using CT and MRI imaging](#), Medical Image Computing and Computer Assisted Intervention (MICCAI), Beijing, China, September 20-24 2010.

Reporting Period 2

Carotti A, Albanese SB, Filippelli S, Ravà L, Guccione P, Pongiglione G, Di Donato RM, Determinants of outcome after surgical treatment of pulmonary atresia with ventricular septal defect and major aortopulmonary collateral arteries., J Thorac Cardiovasc Surg. 2010 Nov

Gagliardi MG, Papavasileiou L, Pongiglione G., Rescue treatment by percutaneous closure of interatrial septal defect or PFO in infants with Berlin heart., Catheter Cardiovasc Interv. 2011 March

Tuo G, Volpe P, Bondanza S, Volpe N, Serafino M, De Robertis V, Zannini L, Pongiglione G, Calevo MG, Marasini M., *Impact of prenatal diagnosis on outcome of pulmonary atresia and intact ventricular septum.*, J Matern Fetal Neonatal Med. 2011 Jun

Ionasec R., Suehling M., Comaniciu D., [Sim-e-Child: Grid-Enabled Platform for Simulations in Paediatric Cardiology Toward the Personalized Virtual Child Heart – VPH NoE 2010](#)

Voigt, T. Mansi, V. Mihalef, R. Ionasec, A. Calleja, E. Mengue, P. Sharma, H. Houle, B. Georgescu, J. Hornegger, D. Comaniciu: *Patient-Specific Model of Left Heart Anatomy, Dynamics and Hemodynamics from 4D TEE: A First Validation Study*, Sixth International Conference on Functional Imaging and Modeling of the Heart, FIMH 2011, May 25-27, 2011.

V. Mihalef, R. Ionasec, G. Georgescu, I. Voigt, M. Suehling, D. Comaniciu: [Patient-specific modelling of whole heart anatomy, dynamics and haemodynamics from four-dimensional cardiac CT images](#), Royal Society Interface Focus Journal, June 6, 2011.

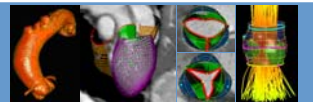
This article, a preliminary version of which had first been presented at the Virtual Physiological Human Conference 2010, Brussels 2010, has been highlighted in the cover page of the Royal Society's Interface Focus journal:

Vitanovski, D., Tsymbal, A., Ionasec, A., Greiser, A., Schmidt, M., Mueller, E., Lu, X., Funke-Lea, G., Hornegger, J., Comaniciu, D., *Accurate Regression-based 4D Mitral Valve Surface Reconstruction from 2D+t MRI Slices; in Machine Learning in Medical Imaging*, MICCAI Workshop 2011.

Ralovich, K., Ionasec, R. I., Mihalef, V., Georgescu, B., Everett, A., Navab, N., and Comaniciu, D., *Computational Fluid Dynamics Framework for Large-Scale Simulation in Pediatric Cardiology*; in Computational Biomechanics for Medicine VI (CBM6), MICCAI Workshop, 2011.

T6.5 Community Liaison and Feedback

During the course of the second reporting period the SeC partners prepared the ground work of the continued development of Health-e-Child's (HeC) original work and the on going work of SeC. In the third reporting period it is expected that the SeC partners in addition to others, possibly including an array of HeC partners, will submit a proposal at the FP7-ICT-2011-9 call, Objective ICT-2011.5.2 2011.



To date the liaison work has focused around the paediatric digital repository that OPBG is developing based around the tools, applications and approach that HeC took towards integrating data and providing clinicians with the ability to search for similar patients and discover new knowledge from linked electronic health records. More information can be found about this ongoing work, where it is the centre piece of SeC integrated exploitation goal, below in T6.6.

SeC and the VPH Community

On behalf of the SeC project, Siemens Corporate Research in the US and Siemens AG in Germany produced an article for the VPH Network of Excellence's 2011 edition of their newsletter. The piece entitled "Sim-e-Child: Grid-Enabled Platform for Simulations in Paediatric Cardiology – Toward the Personalized Virtual Child Heart" focused on introducing the VPH community to the work of SeC and the longer term goal of using simulations of cardio-vascular interventions to model morphological changes and their impact on function and hemodynamics to allow clinicians to personalised risk assessment, planning and for the prediction of optimal therapy.

Months 10-20 also saw cooperative work with the VPH community undertaken by Lynkeus and Siemens (with OPBG as an associate partner) which were both part of a failed VPH-FET Flagship Coordination Action proposal that sought to unite three RTD communities – the Virtual Physiological Human Initiative (VPH-I), Computer Assisted Radiology & Surgery (CARS) community, and the Association for Medical Education in Europe (AMEE) to develop radically new, integrative, ICT-facilitated models and solutions for delivering well-being and health services to global citizens. ITsMe² would have tried to realise the most advanced digital representation (or "virtual avatar"), of every individual for life, evolving, 'learning', becoming an increasingly personalised description of our anatomy, physiology, emotional and physical-social environment as new data and information become available.

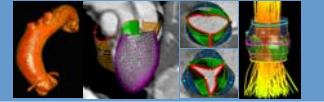
In parallel in Q1 of 2011 OPBG became a "founding member" of the VPH Institute, and Giacomo Pongiglione was appointed as Board Member to the Institute.

SeC and Argos

The SeC partners jointly developed the cardiology section of the ARGOS VPH Policy Brief which was put forward as a proposal for the extension of Memorandum of Understanding that was signed by Vice-President of the European Commission Nellie Kroes and United States Secretary of Health and Human Services Kathleen Sebelius last year as a direct result of Aneesh Chopra, US Chief Technology Officer, positive reaction to it and his recommendation that it should be extended to more advanced technologies, such as VPH. Specifically, Edwin Morley-Fletcher from Lynkeus was invited to coordinate the development of a summary of the success stories in EU-US collaboration on VPH research for cardiology, where SeC was identified as:

Developing the first grid-enabled trans-Atlantic platform for large-scale simulations in paediatric cardiology and offering an online collaborative environment for the construction and validation of multi-scale personalised simulations of a growing heart and vessels. Thanks to this EU-US collaboration, SeC is bringing forward HeC's promising anatomical and physiological models. Three of SeC's most advanced research areas are:

SeC/HeC heart modelling capabilities being validated on an FDA clinical trial database (i.e. the Coarctation Of the Aorta Stent Trial [COAST] by the Johns Hopkins University hospital, in collaboration with the American College of Cardiology, and on newly collected independent MR data at Johns Hopkins and Bambino Gesù hospital in Rome,



Based on high-quality models of patient-specific geometry and dynamics, SeC's "Cardiac Hemodynamics Computation" tool being developed to simulate and analyze the blood hemodynamics within a child's heart and the ascending aorta and aortic arch,

SciPort, an online facility for sharing scientific experiments, providing users with a multi-site, Web-accessible database of SeC's paediatric cardiology data, information and knowledge for translational research and to support the definition, execution and sharing of scientific cardiac modelling and simulations.

Thanks to its enabling trans-Atlantic cooperation, SeC's goal is to ultimately provide clinicians with a model-driven decision support system capable of better personalising congenital aortic disease treatment and assessing when to intervene on patients

A copy of the study can be downloaded here: www.biomedtown.org/argos/reception/brief

T.6.6 Impact of Health-e-Child Conclusion and Further Exploitation Plans

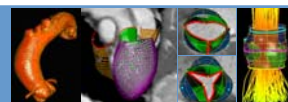
The conclusion of the HeC project in April 2010 did not have any negative impacts on SeC in the second report period.

An integrated exploitation goal in addition to the exploitation plans of each partner if being designed and developed to be focused around the development of a Paediatric Cardiology Digital Repository at OPBG. A full description of the concept and the on going work can be found in Section 3.4.5.

Use of Resources and Deviations between Actual and Planned Person-Months

The actual and planned effort person-months per beneficiary for WP6 are shown in Table 6. Overall, the efforts are considered to be in line with the planned efforts. One main focus of Project Period 3 will be on dissemination and exploitation activities as the technology matures even further and clinical validation results will become available. The remaining efforts have been allocated for this purpose.

WP6 Part. No.	Partic. Short Name	WP6 P1	WP6 P2	WP6 P3	WP6 Cumulative Effort Since Start	WP6 Funded Effort Whole Project	WP6 Unfunded Effort Whole Project	WP6 Total Effort Whole Project	WP6 Remaining Effort
1	Siemens	0.1	0.1		0.2	1		1	0.8
2	Lynkeus	3.05	2.3		5.35	6		6	0.65
4	MAAT	0	1		1	1	2	3	2
5	TUM	0	0.5		0.5	1		1	0.5
6	OPBG	0	0		0	1		1	1
7	SCR	0.3	0.45		0.75	1		1	0.25
8	JHU	0	0.1		0.1		1	1	0.9
10	ACCF	0	3		3	5		5	2
11	PSE	0	0		0			0	0



Total		3.45	7.45	0	10.9	16	3	19	8.1
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Table 6: Actual and planned effort person-months per beneficiary for WP6

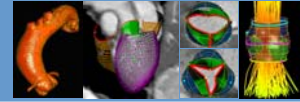
According to Deliverable D1.2 "Self-Assessment Plan" the progress of WP6 is assessed as follows:

Objective No	Objective	Measurement process and units	Assessment
1	To disseminate technical and scientific project outcomes within the academic and public domains, coordinating all the project dissemination activities.	Publication of the project's website	The SeC website was published in the first 2 months of the project in reporting period 1 and the website was updated in the second reporting period
2	To participate and organise conferences, seminars, and workshops in Europe as well as in the USA.	Number of seminars organised in 30 months	6 conferences: (VPH 2010, Health Informatics New Zealand 2010, ConHIT, Paediatric & Adult Interventional Cardiac Symposium, Association for European Paediatric Cardiology, MICCAI 2011)
3	To publish the project's newsletter.	Timely issuing and outreach increase	There was no delay: The first newsletter was published on-time in month 12 and the second is on course to be published on time in month 24. The first newsletter was updated in month 16 to take into account new developments to be disseminated at pan European conferences.
4	To collaborate with other projects and research initiatives.	N. of collaboration with other projects	4 collaborations (VPH NoE, VPH-I, Argos, CARS)

3.3.7. Overall Work Progress and Efforts

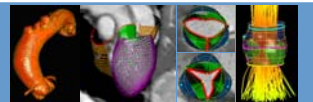
The overall actual and planned effort person-months summing up efforts from WP1 to WP6 per beneficiary are shown in Table 7. Overall, actual efforts are considered to be in line with the planning. Remaining efforts of clinical partners will be spent on the clinical assessment of the technology during Period 3. Parts of the remaining efforts of P10 ACCF have been allocated to fund ongoing data collection driven by P8 JHU. The corresponding amendment request is currently being processed.

WP1-6	Partic. Short	WP1-6	WP1-6	WP1-6	WP1-6	WP1-6	WP1-6	WP1-6	WP1-6
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Part. No.	Name	P1	P2	P3	Cumulative Effort Since Start	Funded Effort Whole Project	Unfunded Effort Whole Project	Total Effort Whole Project	Remaining Effort
1	Siemens	1.52	10.3		11.82	16	3	19	7.18
2	Lynkeus	5.55	3.4		8.95	10	0	10	1.05
4	MAAT	10	9		19	21	3	24	5
5	TUM	1	17.5		18.5	16	1	17	-1.5
6	OPBG	15.3	17.3		32.6	53	1	54	21.4
7	SCR	5.22	4.6		9.82	13.75	1	14.75	4.93
8	JHU	1	3.3		4.3	0	45	45	40.7
10	ACCF	0	3		3	31	1	32	29
11	PSE	5	8.5		13.5	17.5	0	17.5	4
Total		44.59	76.9	0	121.49	178.25	55	233.25	111.76

Table 7: Overall actual and planned effort person-months per beneficiary for WP1 to WP6



3.4. Project Management during the Period

3.4.1. Consortium Management Tasks and Achievements

During the second reporting period, which lasted from November 2010 to August 2011, SeC was managed by P1 Siemens and P2 Lynkeus. During this period the following major management concerns were:

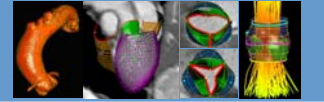
- An extended analysis of the US COAST and GenTAC trial data revealed that pre-interventional MRI data is not part of the COAST protocol and that the GenTAC image data is not suitable for the specific needs of the comprehensive modelling in SeC (see Deliverable D3.1 for details). Consequently, plans were worked out to collect the missing data from enrolled clinical trial patients. P8 JHU filed IRBs accordingly to get ethical approval. P10 ACCF agreed to devote parts of its funding to support the additional efforts needed for the data collection. A corresponding amendment request to re-assign funding was sent to the Project Officer in May 2011 and is currently being processed.
- During the first project period, it turned out that the existing HeC data base lacks patients with high-resolution 3D MRI data (e.g. 3D SENSE protocols). The existing data is mostly based on 2D imaging protocols being inappropriate for detailed modelling of the cardio-vascular anatomy. P6 OPBG has amended its local SeC protocols and has received approval from its IRB to acquire high-resolution 3D MRI scans from selected daily routine patients. OPBG estimates to obtain data from about 140 patients by the end of the project. To account for these additional efforts, OPBG requested to transfer budget from its original “other direct costs” budget to “personnel costs”. A corresponding amendment request to re-assign funding was sent to the Project Officer in June 2011 and is currently being processed.
- As discussed already during the first project review, original plans to install a Grid node at P8 JHU turned out to impact the JHU IT infrastructure. Therefore, it was decided to rent server infrastructure resources from an appropriate Cloud service provider. This also provides more flexibility on the availability of computing resources that can be adapted based on the given needs to run simulation and validation experiments. P4 Maat, as the partner responsible for developing the Grid-based infrastructure, is in charge of renting and operating the Cloud resources. Accordingly, the budget originally assigned to P7 SCR for hardware purchase will be partially transferred to P4 Maat. A corresponding amendment request to re-assign the funding was sent to the Project Officer in June 2011 and is currently being processed.

Even though the requested amendments are undergoing formal approval, the consortium has been working towards the changed plans as described in Section 3.3.

3.4.2. SeC Website

The SeC website (www.sim-e-child.org) went live in the first quarter of 2010 in advance of the conclusion of the HeC project. The website was designed to be completely compatible with the directions laid out by the EC for all dissemination materials and Annex II of the Grant Agreement. The website currently contains sections entitled:

- About
- Partners
- Events
- Public Documents
- Newsletter
- Validation Studies (New)
- Publications
- Links



- Health-e-Child
- Contacts

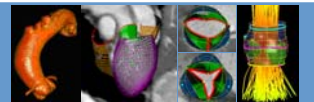
Over the summer of the 2011 a new section of the website was added entitled “SeC Clinical Validation Studies”. The rationale and motivation for this addition can be found in “T6.1 Project Website”.

3.4.3. Project Meetings

Project meetings play a key role in the coordination and synchronization of activities among the partners, as they have fostered communication between the beneficiaries and synergies and cross-fertilization of approaches and results.

The meetings of Period P2 are listed in Table 8, specifying venues, dates, participants, and meeting purpose.

Date & Venue	Participants	Meeting Purpose
03.02.2011, Brussels, Belgium	Siemens Lynkeus Maat TUM OPBG SCR JHU ACCF	- Whole team project meeting in conjunction with the project review taking place in Brussels one day later - Project planning for the second period of the project
18.03.2011, Erlangen, Germany	Siemens TUM	- Synchronization meeting between Siemens and TUM on anatomical modelling and visualization work items
5.-7.04.2011, Berlin, Germany	Siemens Lynkeus	- Presentation of Sim-e-Child project on conhIT Healthcare IT conference. - Discussion of project management tasks
2.-3.05.2011, Rome, Italy	Siemens TUM OPBG Lynkeus	- Attendance of MRI patient scans - Discussion of technical development status and clinical requirements with OPBG clinicians - Planning of clinical validation studies with focus on aorta modelling
24.-26.05.2011, Rome, Italy	Siemens OPBG	- Joined work on clinical validation of aorta modelling - Preparation of conference paper submitted to the American Heart Association (AHA) annual conference
11.-22.07.2011, Princeton, USA	TUM SCR	- Two-week visit of Kristof Ralovich from TUM at SCR. Joined work on simulation platform.
21.07.2011, Baltimore, USA	TUM SCR JHU	- Discussion of technical development status and clinical requirements with JHU clinicians - Planning of clinical validation studies
04.08.2011, Rome, Italy	Siemens Lynkeus TUM	- Discussion of technical development status with OPBG clinicians - Planning of clinical validation studies with focus on haemodynamics simulation



	OPBG	
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Table 8: Project Meetings Overview

In addition to these physical meetings, a monthly management team phone conference took place (every second Monday of each month) to synchronize on the overall project status between all partners. In addition, many ad hoc phone conferences took place between different partners to clarify technical and clinical points. Partners P1 Siemens and P5 TUM had several on-site meetings in Erlangen to synchronize on the development. Overall, phone conferences have proven to be a very useful (and cost-effective) means of sharing information also across the Atlantic.

3.4.4. Project Planning and Status

According to Annex I, Description of Work, the focus of work during the third reporting period will be on Phase 4 of the project:

Phase 4 (running from month 21 to 30) – Extended Models and Final Clinical Assessment: This project phase will capitalize upon the delivered web portal and reference database to support continuous clinical cooperation. Further developments of the portal will be based on the revised requirements as issued at Month 20, while end-users will finalise clinical validation of new models, using the simulation facilities, due at Month 30. From Month 20 onward the collaboration and simulation facilities will be made available to project end-users and to the wider VPH community with a final system release planned at Month 30.

Special management attention will be given to the following two priorities:

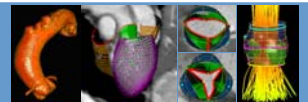
- As the technology and infrastructure developed in Project Period 1 and 2 matures, the work focus will shift towards carrying out clinical experiments and validation studies. Possible validation studies have been discussed and planned extensively among technical and clinical project partners during Project Period 2 as documented in D3.1 “Aligned Clinical Protocol and Assessment Report”. Management activities will focus on coordinating the clinical assessment studies by tracking their progress, arranging synchronization meetings where needed and ensuring technical support to the clinical partners to avoid time delays due to technical issues.
- As clinical results will become available during the last project period, a major focus will be on dissemination and exploitation activities. For details on planned activities we refer to Section 3.4.5.

3.4.5. Project Exploitation Plans

With the project entering the third and last project period and the technical and clinical work maturing, the consortium paid special attention on working out exploitation plans and potential business cases for the research work carried out. As referred to in T6.6, in addition to each partner developing their own exploitation plans and integrated exploitation goal based around the development of a Paediatric Cardiology Digital Repository, which is currently being developed at OPBG with MAAT, at the focal point.

An integrated exploitation goal:

The work that was conducted in the closing stages of HeC to develop an integrated exploitation plan based on the future work of SeC and the development of a Paediatric Cardiology Digital Repository (PCDR) at OPBG has continued. Just as HeC’s work led into SeC, the expected exploitation of SeC’s results is planned to build on the exploitation of HeC by focusing around adding further functionalities to the PCDR, for which the first development stage is expected to be completed in H1 of 2012. The PCDR has been designed also to allow for the future grid or cloud based exploitation of OPBG’s paediatric cardiology data from all of its 5 sites (2 of which are in Sicily), it is thought of as a first stage realisation of what is expected to become, in the future, a Medical Information & Model Management



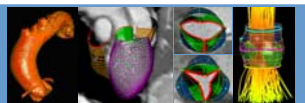
System, a generic information technology framework for the collection, organisation, and utilisation of heterogeneous medical information, ranging from sources such as EHRs to Imaging Analytics, or even to fundamental research knowledge and information extracted from Model-Guided Medicine. As was foreseen in HeC's final exploitation plan, MAAT has been the primary technological partner but in recent months current SeC partners (such as JHU, SCR and Siemens AG), and former HeC partner (i.e. University of Athens) have been brought into the conversation about the direction the second stage of development should take.

It is expected that the PCDR's second stage of development will see the addition of tools like the CaseReasoner, from Siemens, and AITION, from the University of Athens, which will enable clinicians to search for similar patients and discover knowledge from the integrated patient data sets that will be stored on the PCDR. The SeC consortium is also currently looking at other sources of funding which may support the next stages of the PCDR's development. It is the belief of the SeC consortium that the research work of SeC, building on the success of HeC, and the ongoing development of the PCDR, which is also a child of the EC's funding for HeC, puts the SeC project and the extended HeC community in a good position for submitting a proposal to the objective ICT-2011.5.2 of the FP7-ICT-2011-9 call. This objective will in fact fund the development of ICT tools, services and infrastructure to obtain more elaborate and reusable multi-scale models and large repositories to show the benefits of having both the data and models readily available to clinicians, and to develop a VPH Infostructure including sustainable VPH models and data repositories with appropriate tools to improve the accessibility and evolution of eHealth repositories.

At P1 Siemens, internally-communicated SeC project results have generated great interest and excitement in the related operational Business Units, especially at the Computed Tomography, Angio- and Interventional X-ray, and Magnetic Resonance divisions. As the overall business focus evolves from mainly diagnostic products to increasingly support therapy planning and guidance, SeC activities clearly pave the way towards this direction. Siemens' strategy is to boost the links between imaging and therapy for the benefit of the patient, bearing a high market potential.

Within the highly-regulated healthcare market, the productization of decision support technology, as developed in SeC in particular, is very complex and requires comprehensive clinical trials to be carried out to prove its safety and efficiency in a clinical routine environment which may even last for several years. Besides the clinical assessment within SeC, clinical evaluations of anatomical models developed in the predecessor project Health-e-Child (HeC) have already been initiated in cooperation with the corresponding Siemens Healthcare Business Units. As a result, a first product for which clinical tests already started at leading European heart centres, will support planning, guidance, and post-procedural assessment of aortic valve procedures in the catheterization lab. But even in this case, the roadmap to commercialization will only become clear after successfully finalizing the time-consuming clinical trials.

Nonetheless, P1 Siemens learned substantially from the experience within HeC and SeC to be able to address the global market for interventional cardiology systems. Major future research and development on the technology and clinical validation will be crucial to finally arrive at commercial products that are safe and efficient for daily clinical use. Future VPH funding opportunities will have a high impact if utilized to leverage and further develop the existing platform and clinical assessment. In particular, the SeC Grid-enabled infrastructure for data management and distributed high-performance computation is likely to play a key role in this development as it addresses the needs of a globally-distributed market.

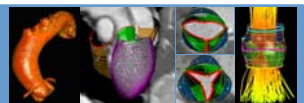


4. Deliverables and milestones tables

4.1. Deliverables

Table 9: Deliverables

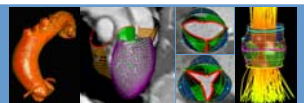
Del. no.	Deliverable name	Version	WP no.	Lead beneficiary		Dissemination level	Delivery date from Annex I (projected month)	Actual / Forecast delivery date Dd/mm/yyyy	Status Non submitted/ Submitted	Contractual Yes/No	Comments
D1.1	Project Presentation	1	1	Lynkeus	R	PU	M5	14/07/2010	Submitted	Yes	
D1.2	Self-Assessment Plan	1	1	Lynkeus	R	RE	M5	14/07/2010	Submitted	Yes	
D1.3	Quality Assurance Guidelines	1	1	Siemens	R	RE	M10	30/12/2010	Submitted	Yes	
D1.4.1	Periodic Report	1	1	Siemens	R	RE	M10	30/12/2010	Submitted	Yes	
D1.4.2	Periodic Report	2	1	Siemens	R	RE	M20	29.10.2011	Submitted	Yes	



D1.4.2 Periodic Report 2

Sim-e-Child (SeC) FP7-ICT-2009-4 (248421)

D1.4.3	Final Report		1	Siemens	R	RE	M30			Yes	
D1.5	Awareness and Wider Societal Implications	1	1	Lynkeus	R	RE	M30			Yes	
D2.1	Initial Interoperability Requirements Analysis Document	1	2	Siemens	R	RE	M10	30/12/2010	Submitted	Yes	
D2.2	Revised Interoperability Requirements Analysis Document	2	2	Siemens	R	RE	M20	02/09/2011	Submitted	Yes	
D3.1	Aligned Clinical Protocol and Assessment Report	1	3	OPBG	R	RE	M5	14/07/2010	Submitted	Yes	
D3.2	Data Model Mapping Report	1	3	MAAT	R	RE	M10	30/12/2010	Submitted	Yes	
D4.1	Grid and Databases Connection Report	1	4	MAAT	R	RE	M10	30/12/2010	Submitted	Yes	
D4.2	Simulation and Collaboration Platform Interim Release and	1	4	MAAT	P	RE	M20	02/09/2011	Submitted	Yes	



D1.4.2 Periodic Report 2

Sim-e-Child (SeC) FP7-ICT-2009-4 (248421)

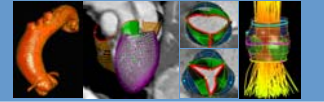
	Report										
D4.3	Simulation and Collaboration Platform Final Release and Report	2	4	MAAT	P	PU	M30				Yes
D5.1	Health-e-Child Heart Models Clinical Validation Report	1	5	JHU	R	RE	M10	30/12/2010	Submitted		Yes
D5.2	Left Heart Model Extension and Delivery Report	1	5	SCR	R	RE	M20	02/09/2011	Submitted		Yes
D5.3	Left Heart Models Clinical Validation Report	2	5	SCR	R	RE	M30				Yes
D6.1	Dissemination Strategy Plan and Preliminary Materials	1	1	Lynkeus	R	PU	M10	30/12/2010	Submitted		Yes
D6.2	Updated dissemination materials	2	1	Lynkeus	R	PU	M20	02/09/2011	Submitted		Yes
D6.3	Use and Dissemination	1	1	Lynkeus	R	RE	M30				



D1.4.2 Periodic Report 2

Sim-e-Child (SeC) FP7-ICT-2009-4 (248421)

	of Foreground (Final Report)									Yes	
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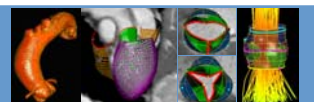
4.2. Milestones

The main target during Project Period P2 was to achieve Milestone M3 (Please see Table 10 for an overview of all project milestones). Milestone M3 is defined as:

First Version of Simulation and Collaboration Platform: First version of portal allowing access to simulation platform (D4.2) with left heart model (D5.2) established and validated against requirements (D2.2).

With all relevant deliverables submitted and first simulation experiments carried out using the simulation and collaboration platform, this milestone is considered to be passed as planned for.

Table 10: Milestones							
Milestone no.	Milestone name	Work package no	Lead beneficiary	Delivery date from Annex I dd/mm/yyyy	Achieved Yes/No	Actual / Forecast achievement date dd/mm/yyyy	Comments
M1	Aligned Clinical Protocols and Assessments	WP3	OPBG	M5	Yes	M5	
M2	Grid Connection, Interoperable Databases, Health-e-Child Validation	WP2, WP3, WP4, WP5	MAAT	M10	Yes	M10	
M3	First Version of Simulation and Collaboration Platform	WP2, WP4, WP5	Siemens	M20	Yes	M20	
M4	Simulation and Validation results for Left Heart Models	WP4, WP5	Siemens	M30	No	M30	

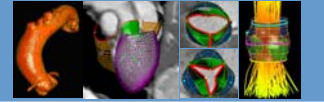


5. Explanation of the use of the resources

The use of resources is explained for each beneficiary in the following tables.

Table 11: Personnel, subcontracting and other major cost items for Beneficiary 1 Siemens for the period			
Work Package	Item description	Amount in € with 2 decimals	Explanations
WP 1-6	Personnel direct costs	85,220.32	Personnel costs for 3 full-time employees partially involved in the project.
	Subcontracting	0.00	
	Remaining direct costs	0.00	
	Indirect costs	71,111.68	Indirect costs also cover the work of one PhD student involved in the project.
TOTAL COSTS		156,332.00	

Table 12: Personnel, subcontracting and other major cost items for Beneficiary 2 Lynkeus for the period			
Work Package	Item description	Amount in € with 2 decimals	Explanations
WP1	Personnel direct costs	5.993,68	Two Senior Managers and one Junior Manager were involved in the ongoing operations of the project.
WP6	Personnel direct costs	14.820,80	Two Senior Managers, one Junior and the IT Manager were involved in various Dissemination activities with regard to Conh-IT attendance, presentations in clustering events, preparation of the Sim-e-Child newsletter and website development and content management.
WP6	Major cost item:	1.039,30	Travel and accommodation costs, printing of newsletter and flyers for presentation of SeC and networking at Conh-IT in Berlin April 5-7 2011
	Indirect costs	9.178,59	42% of direct costs



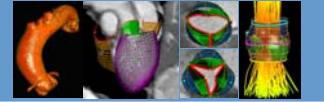
TOTAL COSTS	31.032,37	
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Table 13: Personnel, subcontracting and other major cost items for Beneficiary 4 Maat for the period

Work Package	Item description	Amount in € with 2 decimals	Explanations
WP2, 3, 4, 5 and 6	Personnel direct costs	50,444.00	Salaries of 3 FTEs partially involved in the project.
	Remaining direct costs	3,678.00	Project hardware amortization
	Indirect costs	30,266.00	Indirect costs
TOTAL COSTS		84,388.00	

Table 14: Personnel, subcontracting and other major cost items for Beneficiary 5 TUM for the period

Work Package	Item description	Amount in € with 2 decimals	Explanations
	Personnel direct costs	73,791.46	K. Ralovich November 2010 – August 2011 A. Eslami February – August 2011
	Subcontracting	0.00	
	Remaining direct costs	5,638.62	444,44 HDD 72,27 HDD Verbatim 224,56 HSSD Vertex 45,71 Mouse Logitech 56,60 spare parts 32,80 Depreciation Monitor 2011 180,00 Depreciation Lenovo Thinkpad 185,36 Laptop Case, Keyboard 295,06 Depreciation PC Alienware DELL 105,51 Depreciation DELL Notebook 150,28 Depreciation DELL Precision 54,80 Lifecam studio 750,77 K. Ralovich Rome May 2011



			278,65 A. Eslami Rome May 2011 60,36 K. Ralovich Erlangen March 2011 60,36 K. Ralovich Erlangen April 2011 679,52 K. Ralovich Brussels Feb 2011 696,49 A. Eslami Brussels Feb 2011 64,36 K. Ralovich Erlangen Jan 2011 732,52 K. Ralovich Weltenburg 2010 59,46 K. Ralovich Erlangen Jan 2011 251,14 K. Ralovich Erlangen Dec 2010 157,60 K. Ralovich Erlangen Oct 2010
	Indirect costs	47.658,05	
TOTAL COSTS		127.088,13	

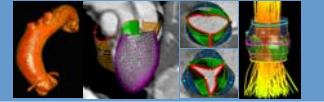


Table 15: Personnel, subcontracting and other major cost items for Beneficiary 6 OPBG for the period

Work Package	Item description	Amount in € with 2 decimals	Explanations
	Personnel direct costs	41.425,00	Salaries of 2 post-doctoral students (Euro 31.425) and salaries of OPBG personnel unfunded
	Subcontracting		
	Major cost item 'Meetings'	1.874,47	Meeting Bruxelles Euro 876,31; Meeting Istanbul Euro 998,16
	Remaining direct costs		
	Indirect costs	16.540.40	Overheads 38,2%
TOTAL COSTS		59.839,87	

Table 16: Personnel, subcontracting and other major cost items for Beneficiary 7 SCR for the period

Work Package	Item description	Amount in € with 2 decimals	Explanations
WP 1, 2, 4, 5, 6	Personnel direct costs	39,732.38	Personnel costs for 6 staff members partially involved in the project.
	Subcontracting	0.00	
	Remaining direct costs	2,556.23	Meeting in Brussels for first project review and meeting at JHU jointly with TUM.
	Indirect costs	17,190.80	
TOTAL COSTS		59,479.41	

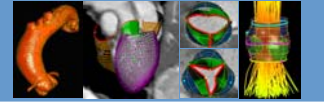
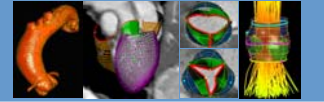


Table 17: Personnel, subcontracting and other major cost items for Beneficiary 8 JHU for the period

Work Package	Item description	Amount in € with 2 decimals	Explanations
WP 1-6	Personnel direct costs	0	Efforts of clinical staff members for: - Coordination of pre-interventional MRI data collection from COAST trial partner centers (among others: revision and submission of an addendum of the COAST study to individual IRBs) - Data collection at JHU from patients with genetic aortic aneurysms (including IRB approval) - Discussion of clinical requirements and validation of developed modelling and simulation platform. - Contributions to clinical validation and scientific publications. - Contributions to dissemination activities such as an article together with P10 ACCF.
	Subcontracting	0	
	Major cost items	0	
	Remaining direct costs	0	
	Indirect costs	0	
TOTAL COST		0	

Table 18: Personnel, subcontracting and other major cost items for Beneficiary 10 ACCF for the period

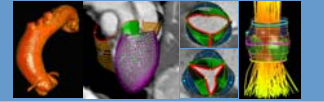
Work Package	Item description	Amount in € with 2 decimals	Explanations
	Personnel direct costs	10,000.00	Management personnel costs. These costs cover ACC Staff management of this project including our International Affairs team as well as the marketing and



			cardiosource staff time.
	Subcontracting	0.00	
	Remaining direct costs	15,315.25	<ul style="list-style-type: none"> - Conference visit and scientific results presentation of Dr. Philip Spevak (P8 JHU) at the 45th Annual Meeting of the Association of European Paediatric Cardiology (AEPC 2011, May 18-21, 2011). - Travel costs for Sim-e-Child consortium meeting and project review participation of Dr. Gerard Martin (ACC), Feb. 3-4 2011, Brussels, Belgium. - Laptop cost for project, shipping and printing costs, taxes and fees.
	Indirect costs	5,063.05	
TOTAL COSTS		30,378.30	

Table 19: Personnel, subcontracting and other major cost items for Beneficiary 11 PSE for the period

Work Package	Item description	Amount in € with 2 decimals	Explanations
	Personnel direct costs	15.994,52	Personnel costs for the following activities: <ul style="list-style-type: none"> - SciPort development - Simulation platform development. Integration of SimSys into Grid framework.
	Subcontracting	0,00	
	Remaining direct costs	0,00	
	Indirect costs	20.935,48	Overhead costs
TOTAL COSTS		36.930,00	



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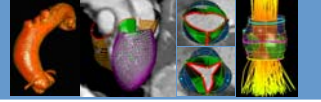
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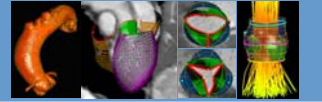
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7. Financial statements – Form C and Summary financial report

The financial statements are attached in the file “D1.4.2PeriodicReport02FormC.pdf”.