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ADAPT: ADAPTIVE MULTI-AGENT PROCESS PLANNING AND COORDINATION OF CLINICAL TRIALS

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Abstract

We present a system for planning; management and decision support of clinical trials and describe the initial system concept, currently implemented or specified functionalities and the integration of FIPA standardization activities. The example scenario “clinical trials” illustrates how the system supports distributed clinical processes and how it interacts with other multiagent systems of the Agent.Hospital Framework introduced in the paper. The system development is part of the German Priority Research Program (SPP) 1083 “Intelligent Agents and their application in business scenarios”

Keywords: Multi-agent systems, simulation, health care, clinical trials

Introduction

Health service in Germany came over the last years to a more and more important field in economic studies. The budget for the German health care increased to 218 Billion € in the year 2000 with a growth of 5-10 % per year. Thus, the current expense of health care is getting an important part of macroeconomics costs. It is expected that information technology plays a main role in reduction of expenses and stabilization of health care budgets. In the domain of hospital logistics complex and highly distributed systems are under research. These systems are designed to analyze the domain as well as to realize software systems esp. for management and control of information flows and business processes. The approaches to this domain are two-fold: On the one hand, simulation systems are used for analyzing the domain, planning and re-engineering of business processes. On the other hand, development of management and control systems for information flow and business processes is of interests.

In this context we urgently need realistic business scenarios. The healthcare domain with its specific requirements is a predestined world of discourse for building realistic scenarios and the application of multiagent systems. Intra-organizational as well as numerous inter-organizational interfaces to different actors along the “supply chain” (for instance rescue service, general practitioner or specialist, rehabilitation etc.) have to be integrated. Raising importance of information systems is interlinked with specific deviations of the (german) healthcare domain (sectoral distribution, decision autonomy of physicians and patients) which blocks top-down-integration of processes and information systems.

Corresponding questions are examined since 2000 by the German Priority Research Program (SPP 1083; <http://www.realagents.org>). The main goal of SPP 1083 is the examination of agent technologies within large realistic business scenarios and the identification of further research needs. One of the examined domain specific scenarios focuses on the healthcare domain. Basic supposition of the SPP is that agent-based development and connection of decentralized information systems generates essential benefit by supporting interorganizational business processes and organizational flexibility. Examination of these hypotheses is supported by large agent-based software systems.

This paper introduces first of all the essential questions and research approach addressed by the ADAPT project as a part of the SPP 1083, the developed system and its integration into the Agent.Hospital Framework (Kirn et al. 03). We introduce participation in the research network Agentcities and corresponding FIPA (<http://www.fipa.org/>) standardization activities. At the end of the paper an example scenario “clinical trials” illustrates how the developed systems support distributed clinical processes.

Motivation and Goals

In cooperation with clinical partners, the scientific objective of the ADAPT project is the optimization of processes and information flow of the participating oncology and radiation therapy departments. As a result of this, resource allocation, time scheduling and tactical planning should be improved with respect to efficiency and control. Gained experiences should allow conclusions about the usability as well as the advantages of agent based software. Specific motives and goals of the project are:

- *Improvement of distributed appointment scheduling* – Appointment scheduling for treatment and examination tasks in hospitals is inherently distributed between various organizational units and there are a lot of interdependencies between the processes of the actors. This fact makes it very difficult to explain effects of single actions and to optimize the process. The scheduling and negotiation strategies used in the general praxis are mainly dominated by simple ad hoc solutions, which can be optimized. Therefore simulation and analysis of scheduling scenarios and finding new more sophisticated processes is an important objective of the ADAPT project. Using clinical trials on chrono-modulated medication, an agent-based system was designed and implemented in order to support the trial scheduling and coordination of patients, medical staff, and equipment.
- *Support for decisions about participation in clinical trials* – Clinical trials obligate the participating hospitals to perform prescribed treatments and examinations. Among the scientific benefit, a calculation of costs has to show whether these incurred liabilities are cost covering or not. According to this, the ADAPT system should allow cost-benefit estimations based on simulations which regard medical considerations and individual preferences. Agent technology is used to handle the high level of environmental dynamics as well as the complex and restrictive requirements of clinical trials. Utilization and trial specific statements are supported by realistic simulation results.
- *Operationalization of study protocols* – Induced by the complexity and regimentation of trial, much effort is needed for the coordination of all involved actors and equipments. Continuative goal of the ADAPT project is to advance the agent based simulation system towards a real-time assistance system that enables online resource allocation. Supporting the operational processes by coordinating the flows of information (adapted to the individual medical pathway), the use of agent technology should result in a higher level of process efficiency.

Agent.Hospital Framework

To evaluate the developed systems a complex and realistic evaluation scenario is needed. Therefore the working group “hospital logistics” of the SPP 1083 including the ADAPT-Project developed an extensive and empirical funded model called *Agent.Hospital* (Kirn et al. 03). This model is an open framework for numerous different healthcare actors. *Agent.Hospital* consists of detailed described partial healthcare models and different kinds of service agents and agent-based platforms. The *Agent.Hospital* framework supports evaluation of modeling methods, the examination of configuration problems as well as the examination of agent-based negotiation strategies and coordination algorithms.

In context of Priority Research program SPP 1083 the involved research partners of the working group “hospital logistics” integrated the partial hospital logistics models created by the participating projects. The involved research groups and application parties offer a wide spectrum of relevant clinical processes. Relevant organizational structures, processes and necessary data models were analyzed, formalized and modeled at several hospitals. To be able to integrate of the different partial models it was necessary to define numerous gateways between these models (see figure 1) and to develop a common ontology for interaction at the gateways. Additionally basic process patterns had to be defined (for instance planning and execution of clinical trials with oncological patients). On the conceptual level *Agent.Hospital* consists of partial models, process patterns, gateway specifications and shared ontologies. The resulting framework is a conceptual overall scenario based on the integrated project specific partial models.

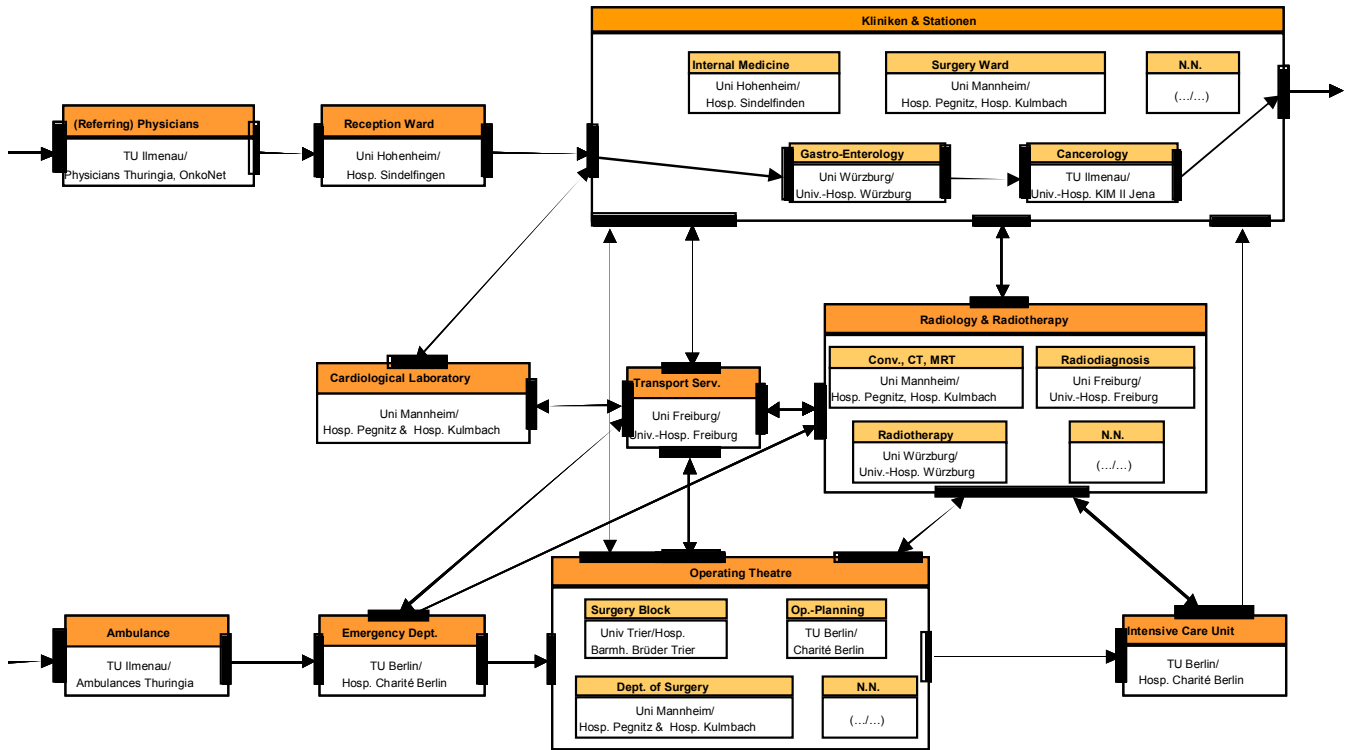


Figure 1. Application Diagram of the *Agent.Hospital* Framework with Several Selected Supply Chains

In *Agent.Hospital* several clinics, departments and wards are defined as service provider and consumer units. In the following the offered and requested services are denoted simply as *services*. For a technical interaction between the service providing and consuming units there is a need to use well defined interfaces based on existing agent communication languages, interaction protocols, content languages as well as on common ontologies.

Currently the following overall supply chains shown in figure 1 are implemented: clinical trials and radio therapeutics (ADAPT), rescue patient (AGIL), lung cancer treatment (ASAINlog), angina pectoris (MedPage), gallstone therapy, surgery processes (Policy Agents), radiological service processes (EMIKA). More details and references to these projects are provided via the RealAgentS – website, the public groupware tool of the SPP.

Important for the development of *Agent.Hospital* was the use of existing and established standards. In agent research the “Foundation for Intelligent Physical Agents” FIPA plays the leading role. During the last years, the FIPA organization has concluded and proposed primarily standards for the design of agent platforms as well as standards for communication and interaction.

Intelligent software agents in application have to be integrated in an existing (often proprietary) information system infrastructure. Therefore, the aim of the hospital logistics working group is implementation, evaluation und documentation of agent based health care services, which are supposed to be base of future FIPA-*Application Specifications*. Since 2002 the priority research program 1083 is member of FIPA and has the task to develop and evaluate examples and to refine the existing application specifications in health care.

Beside the work in FIPA, the SPP 1083 initiated cooperation with the association of information system producers in health care (VHGit), to develop specifications of interfaces between specialized applications (practice systems, patient record, etc.).

Further on, the SPP contributes to *Agentcities* (Willmott et al. 2003), an open, worldwide net of FIPA-compliant agent platforms, on which different agent based services - often in the stage of development - are provided. Currently there are more than 140 agent platforms members of *Agentcities* with a high concentration in Europe and also several platforms in the USA, Australia and the near east.

Within *Agentcities*, a lot of different application domains exist, for instance eHealth, manufacturing control, digital libraries, and travel services and so on. Ultimate aim of the initiative is to support the commercial as well as academic efforts for the realization of agent based applications and to make it possible to compose dynamic, intelligent and autonomous agents to complex service agents.

One goal of *Agent.Hospital* was, to become a part of *Agentcities*. Therefore new *Agentcities* platforms have been set up in five German cities. They are connected by a central directory service (*Agent.HospitalDF*) in Aachen, which registers all participating service agents (see figure 2).

To be a part of *Agentcities* network different services within *Agent.Hospital* are planned or partially developed:

- *Agent.Hospital Directory Facilitator (AHDF)* – http://www-i4.informatik.rwth-aachen.de/agentcities/RWTH_Agentcities_Web_files/hospital.html) a yellow pages service and a web interface. It provides extended functions in comparison to *Agentcities globaldf*.
- *Agent.Hospital EventService (AHES)*: an event service that can be used for event based simulation of multi agent systems in the healthcare domain.
- *Agent.Hospital Ontology Repository (AHOR)*: a repository providing healthcare specific task ontologies on demand.
- *Agent.Hospital Knowledge Base (AHKB)*: a knowledge base based on the domain ontology OntHoS (Becker et al 2002).
- *Agent.Hospital Actor Agent (AHAA)*: another common component to all the involved projects is the Actor agent. Instances of the actor agent represent real actors in *Agent.Hospital* scenarios.
- *Agent.Hospital CVS (AHCVS)*: a repository containing the source files of the service agents based on the CVS.

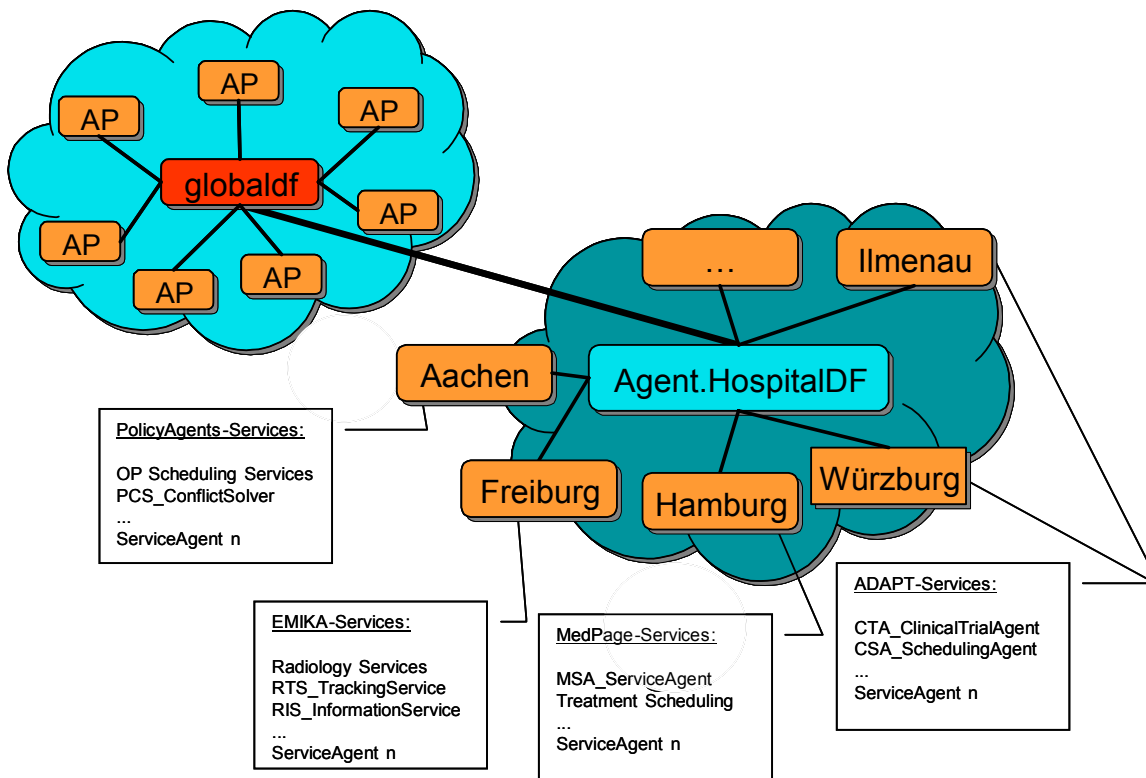


Figure 2. Embedding of Agent.Hospital in the Agentcities.NET Infrastructure

Measures of the query response time made on the described Agent.Hospital DF infrastructure are shown in the figure 3 below. The measures represented in figure 3 are made between a host at the University of Aachen and a client at the University of Ilmenau.

The query response time was measured 50 times for 20 different configurations, while in each configuration the number of agents was incremented by 50 agents. Interesting parameters of the measures made are maximum, minimum, average and median. Usually the average value can be used as a point of reference of future query durations but it is often falsified by single very high response time peaks in comparison with the bulk of response times. Therefore the median value was also computed and is shown. In the local environment (Aachen) the median and the average value of the measured response times are less than 200 ms and in the distributed environment (Ilmenau) less than 400 ms. This values should be considered for query intensive agent applications dealing with time planning, scheduling or resource allocations. Further the maximum values should be considered for real time applications dealing with hard time constraints.

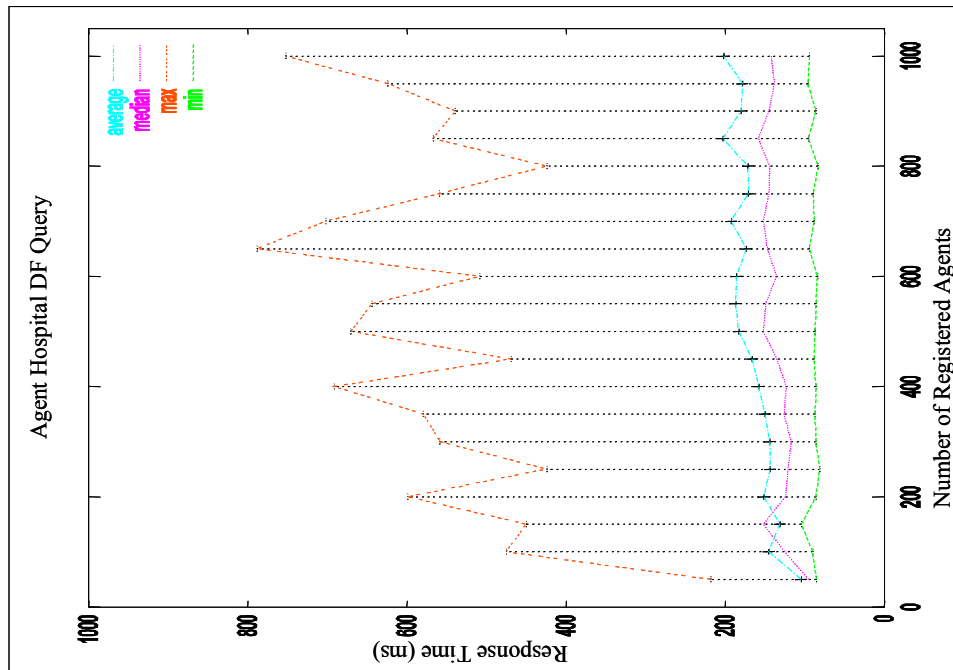


Figure 3. Response Time of the Agent.Hospital DF at the University of Aachen

Our ADAPT project as a part of *Agent.Hospital* is represented with platforms in Würzburg and Ilmenau but at the moment without hard real-time constraints. Focus of the ADAPT-Agents in *Agent.Hospital* is to provide services for treatment planning and for distributed scheduling. We provide decision support in planning and execution of clinical trials as well as services for appointment scheduling for any functional unit.

Technical Base and Challenges

Technical basis of the ADAPT project are two multiagent systems with different foci. The DAISIY-Framework (Deliberative Agents for Intelligent SIMulation SYstems) is a hybrid system that consists of multiagent technology and conventional simulation software. The focus of this approach is to reuse traditional process models and to enrich them with the possibilities of multiagent simulation. SeSAm (ShEll for Simulated Agent systeMs) (Klügl 2001) is an integrated environment for modeling and simulating multiagent systems. The main focus is to provide powerful modeling functions for the easy construction of complex models and to enable domain-experts creating simulation models without programming. Each of the two approaches has its strength respecting the focus. In combination they allow different situation-dependent modeling. The interoperation of the two systems is realized by a FIPA-compliant interface.

DAISIY Framework

Conventional business process modeling is the starting point for creating DAISIY-Simulations. The cooperation of conventional simulation software and one or more multiagent systems makes it possible to integrate new process models (like examinations and medical pathways of clinical trials) in a given simulation environment. Among the integration of new process models, the agents perform the representation of individual decision makers like patients, nurses, or physicians. Personal preferences and individual goals could be implemented in the simulation model for application of this (hybrid) system architecture, assumed the agent architecture allows the integration of goals.

Following the approach to simulation of domains, DAISIY introduces a methodology consisting of five steps:

1. Business process modeling using a standard tool, e.g. ARIS-Toolset=
2. Transfer of data and models into a simulation model, e.g. Simple++ (eM-Plant)
3. Automatic synthesis of generic agent systems from simulation and business process models
4. Enhancement of agent model: Intelligent Agents as substitution for agents along critical paths, in order to preserve structure and behavior of organizations and actors of the real world
5. Detailed simulation using multiagent system

Based on a layered architecture in the DAISIY framework three aspects – real world, simulation, and management – are considered. These aspects are addressed to introduce respective components: modeling for the real world, multiagent system and simulation software for management and simulation. The architecture of this framework including conceptual design of the components can be found in figure 4.

Modeling business processes, organization, and data structures of the real world takes place by using standard modeling tools. These models are used for integrating real world aspects and simulation models. The resulting simulation models combined with a simulation engine are establishing a virtual reality for agents. Temporal and spatial dimensions are generated by the simulation component in order to realize a simulation close to reality. According to this, the simulation aspects are considered by the use of a simulation system and agents.

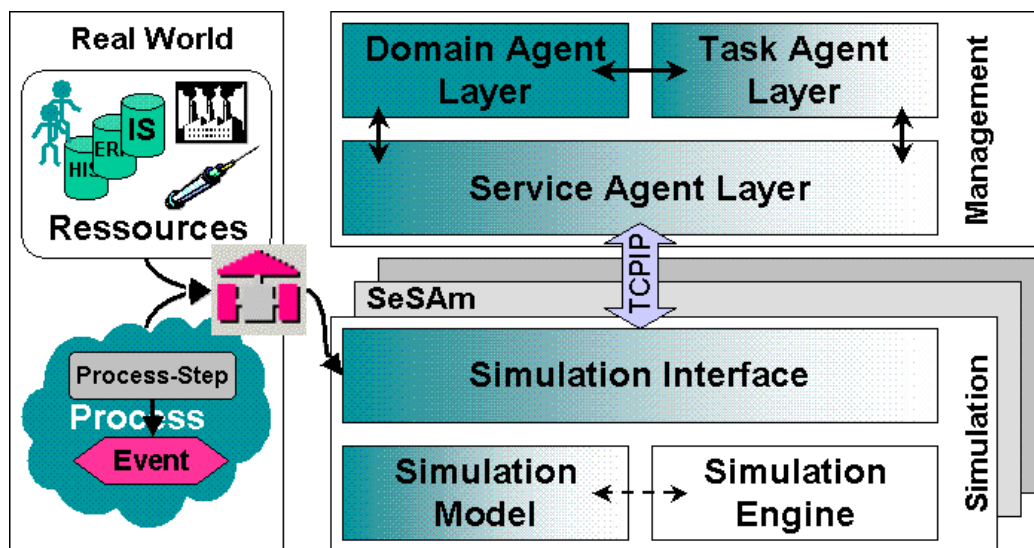


Figure 4. DAISIY Framework

The management aspects are considered within the multiagent system. We propose a layered multiagent system, the DAISY system. Embedded in the virtual reality agents are classified according three purposes. Each class is realized within a layer assigning each agent with specific tasks, which are domain dependent (Domain Agent Layer), domain independent (Task Agent Layer), or services relevant to the DAISY framework (Service Agent Layer).

Management aspects pertaining to the system's operations are supported by agents of the Service Agent Layer. This includes agents for system introspection, agents that interpret and visualize simulation results, and agents enabling the interoperability of the framework components. According to this, service agents perform the synchronization and information exchange of the simulation environment and domain specific agents.

The Domain Agent Layer consists of representation agents reflecting human actors, abstracted organizational units, or technical equipment. These agents incorporate profiles, preferences or simple decision rules of the real world entities. Embedded in the virtual reality, inter-agent operations, e.g. conversation, can be simulated under the restrictions of spatial relations. Task agents, as they are included in the Task Agent Layer, support these activities by offering generic functionalities like complex scheduling algorithms. Otherwise these functionalities have to be internalized in the domain-specific agents.

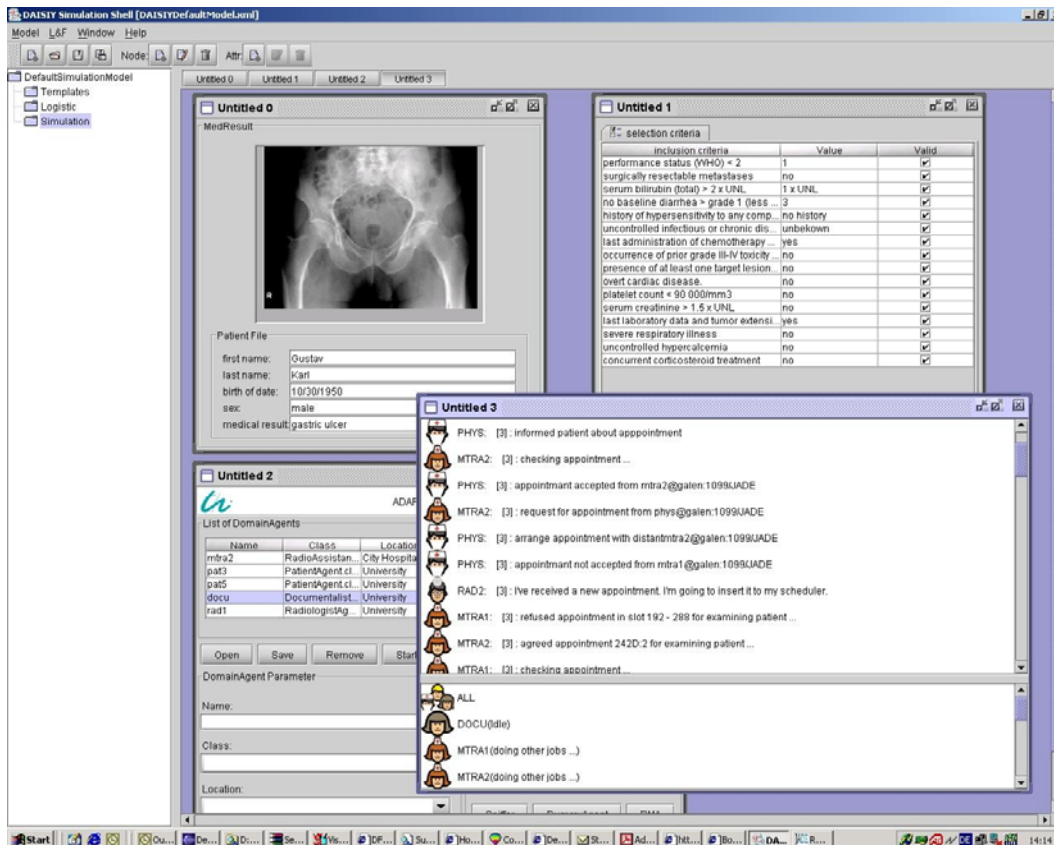


Figure 5. GUI for Agent-Based Management of Clinical Trial

SeSam

SeSam stands for “Shell for Simulated Agent Systems”. It provides a generic environment for modeling and experimenting with agent-based simulations. It allows visual modeling of agents and their environment respecting their properties, abilities and behavior. So it addresses not primarily programmers but domain experts to create simulation models. Different agent classes can be created and their properties and abilities can be defined by adding agent specific attributes and modular features. The set of features can be easily extended and there is already a useful set available like for example “movement”, “evolution” and

“scheduling”. Using this features and the basic set of primitive actions and functions the behavior of the agent can be described. Basic representation of the agents behavior are UML-activity diagrams (see figure 6). They are easy understandable and a common well known notation. Activity diagrams consist of activities and transition rules. The activities can be seen as states containing a series of actions, which are executed until an exit rule activates the next activity. First experience with creating ant models was gained very early (Klügl et al. 1998) but in recent time several additional features to support handling more complex models like healthcare scenarios are integrated in the environment (Oechslein et al. 2002). So among various other features the environment allows hierarchical modeling at the level of function description as well as on the level of behavior description. Basic function primitives can be composed to more complex user defined primitives and parts of the activity graph can be melted together to compound activities. To simplify testing and finding errors in the model it is possible to create rules for invariant states, similar to assertions in modern programming languages. Finally new features support communication as well as ontologies. Here general standards were respected to guarantee the possibility for interoperation with other systems. The new plug-ins provide FIPA-compliant communication primitives and to a possibility to import ontologies modeled with the ontology tool Protegé2000 (<http://protege.stanford.edu/index.html>). After modeling the agent classes, simulation situations can be created on a two dimensional map. For simulation of a scenario this model representation is compiled and can be run directly from within the environment. During simulation is possible to watch the animated map, pause and resume the simulation and to control the agents’ states. A more sophisticated simulation analysis is provided by a flexible analysis component. It allows filtering, processing and generating charts from the simulation data. To get reliable evaluations often a lot of experiments are needed. Therefore you can distribute multiple simulations on different computers within the local network using the SeSAM remote service. So the available computing power can be accessed easily.

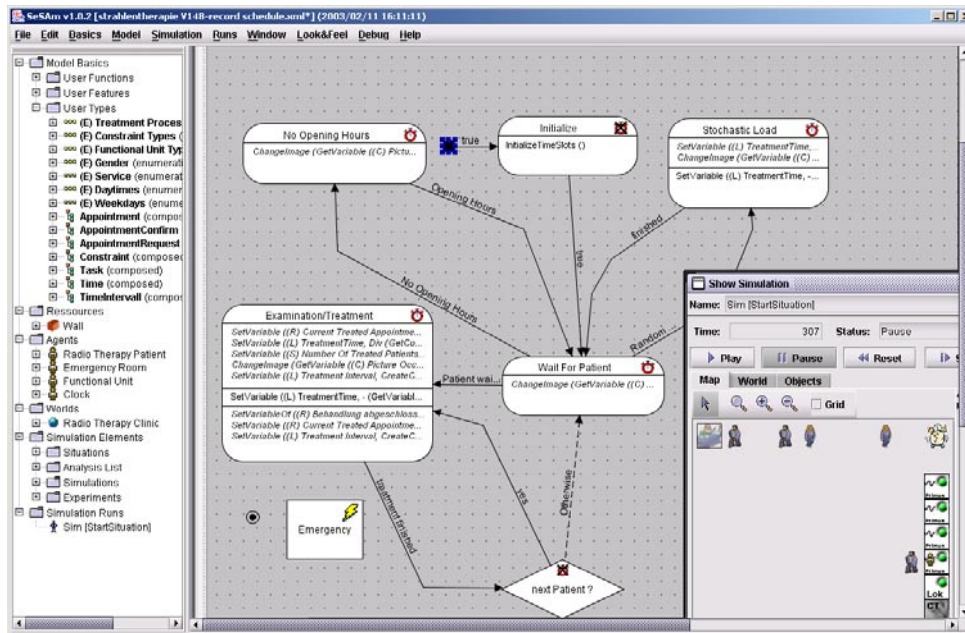


Figure 6. Visual Modeling and Simulation with the SeSAM-Environment

Clinical Trial Scenario

A special and expensive field in health care is the medical treatment of cancer. A lot of costly research has done in the past and much more will be expected in the future. To introduce a new medicine or therapy a lot of medical trials have to be run. Clinical trials are carefully controlled studies in which oncology experts evaluate better ways to treat, prevent, or diagnose cancer. Increasing the number of patients who are enrolled in clinical trials, as they represent an opportunity for patients with cancer to receive the best possible care is really important. Clinical trials are also extremely valuable because they answer important questions that will help to continually improve cancer care and decrease the risk of cancer development.

Before a new therapy or medical treatment can be put into daily clinical therapy, a lot of trials have to be run. Clinical trials are detailed plans for medical treatments, for instance a clinical trial protocol can describe at which point of time, in which quantum,

and how medications or therapies have to be executed. But clinical trials were not performed in linearity; instead their concrete structures depend on particular patient constitutions, laboratory results, etc. Clinical trials are described by graphs, each node representing a particular state of a particular study.

During the execution of medical trials an extensive documentation will be produced with the help of a documentalist. This is important, because clinical trials are paid mainly by pharmacy industry, and they are thus one important business model for university hospitals. At a beginning of study involved hospitals do not know, which costs arise and if the money paid by pharmacy industry is sufficient to realize the trial.

Typical sample sizes for clinical trials require about 150 to 200 patients which make it necessary in general that several hospitals cooperate in performing such trials (multi-centric trials). To identify information flows between the involved hospitals and actors (doctor, nurse, documentalist), we modeled large scenarios with help of ARIS (architecture for integrated information systems) a methodology and a set of tools for developing information models.

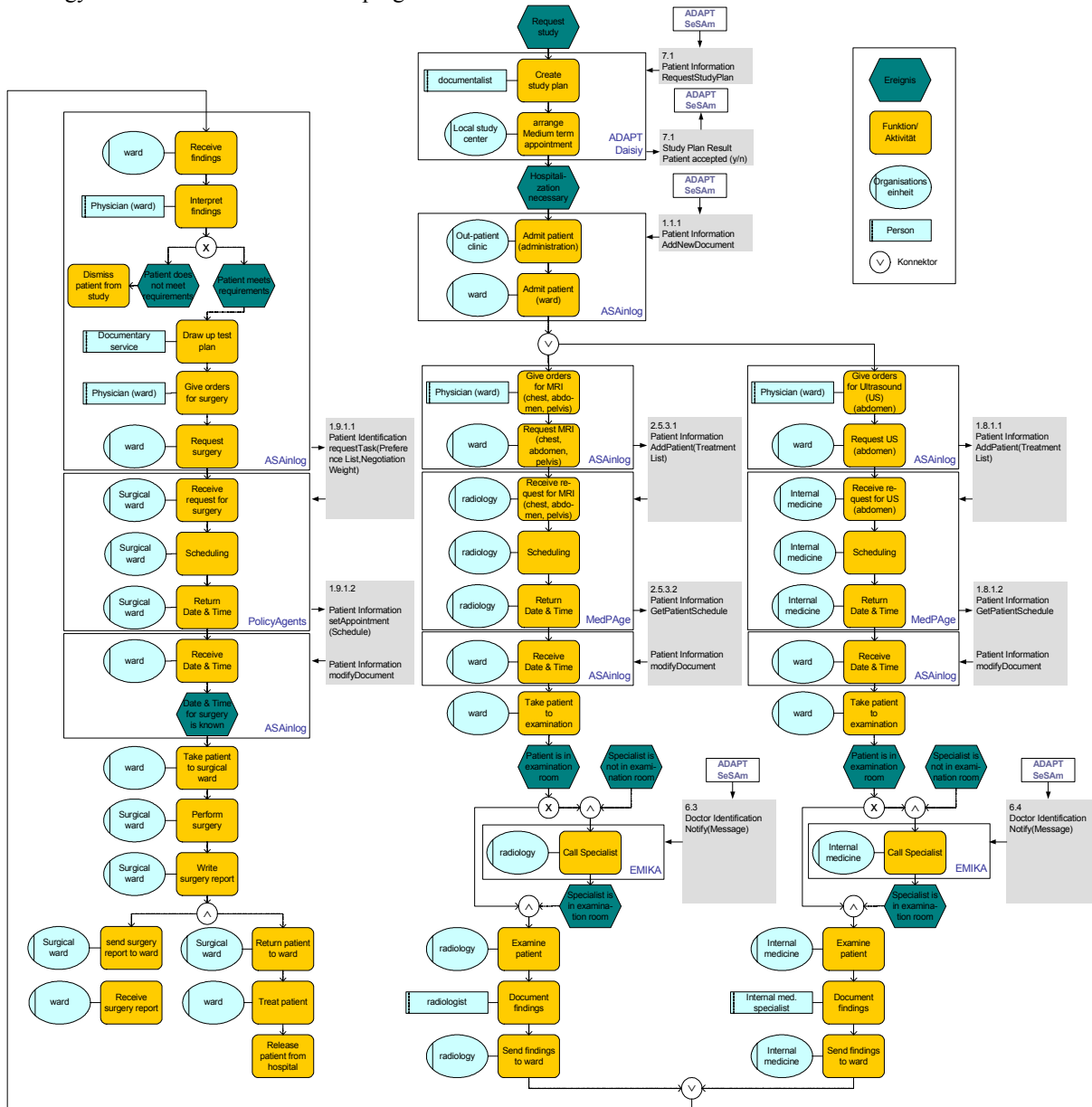


Figure 7. Exemplary Part of the Clinical Trial Scenario with Interactions between Different Multiagent Systems

Figure 7 describes an exemplified process part of the integrated simulation scenario “clinical trial”. The description of the process is similar to the extended event-driven process chains (eEPC). The strict bipartite change from events and functions is repealed to simplify the description of the processes. The simulation according to the process description is directed by SeSAm and utilizes several agent based services provided by the SPP 1083.

At the beginning of a clinical trial various tasks for diagnosis and treatment have to be coordinated and scheduled resources have to be assigned and if necessary informed. Figure 7 shows an example with CT- (computer tomography) und MRT- (magneto-resonance-tomography) examinations as well as execution of a surgery. In a first step, the suitability of the patient for the study will be checked. The DAISIY-System appraises the patient data (regarding specific criteria from the clinical study guidelines) coming from the SeSAm simulation.

The DAISIY user interface agent presents the patient data and the recommendation to the responsible physician, and asks for the affirmation. If the patient fulfils the preconditions for the trial an individual study plan will be created and can be accessed by other agents sending a request message. The concerned documentalist is also able to integrate own demands for appointments into the proposed study plan. After planning the medium term study plan (usually four weeks) for the patient and extending the electronically patient data record further agent services can start the operative planning and scheduling of the mandatory appointments. In case of an emergency surgery of a patient reported by SeSAm, it will be necessary, that the concerned systems for study management and treatment scheduling are able to change the planned appointment.

The following interaction diagram (Figure 8) shows a simplified process of the system interactions within *Agent.Hospital*. Here are just the essential steps depicted and interactions for error handling are not included (e.g. *not-understood, refuse, failure*).

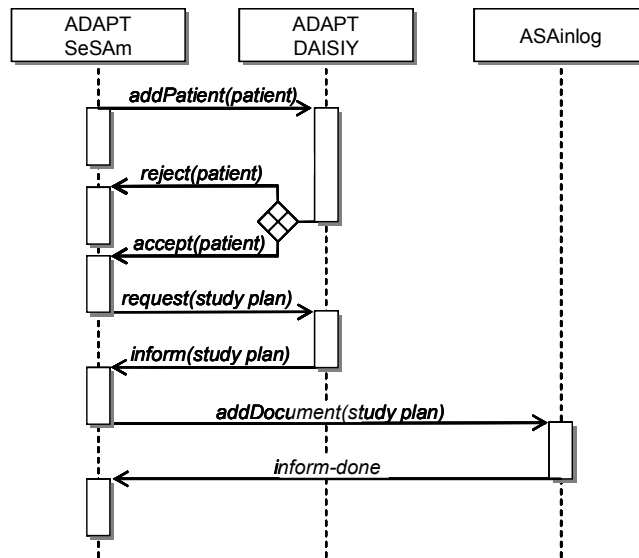


Figure 8. Simplified Interaction Diagram in the Integrated Scenario “Clinical Trials”

Scheduling-Scenario in Radiation Therapy

A different but interconnected scenario concerns scheduling in radiation therapy units. Based on empirical investigations we have implemented a detailed SeSAm model describing the patient scheduling in a clinic for radiation therapy. The clinic consists of a reception, where the patients appointments are planed, waiting rooms and treatment rooms as well as radiation devices. Functional units and devices are all owning specific opening times and a current schedule. One of the typical patient processes for radiation therapy is assigned by the doctor after a patients arrival. The addressed problem is that the schedule of the real treatment execution always differs from the preplanned schedule. Here we wanted to find new scheduling strategies to improve the process respecting predefined quality criterions like waiting time of patients and utilization ratio of resources. Extensions of the model also simulate late patients and uncertain treatment times.

Figure 9 shows a screenshot of a running simulation. The selected patient is waiting in the queue in front of the tumor localization room. This unit has opening hours (shown by the green light) and new patients can get appointments respecting the already planned schedule).

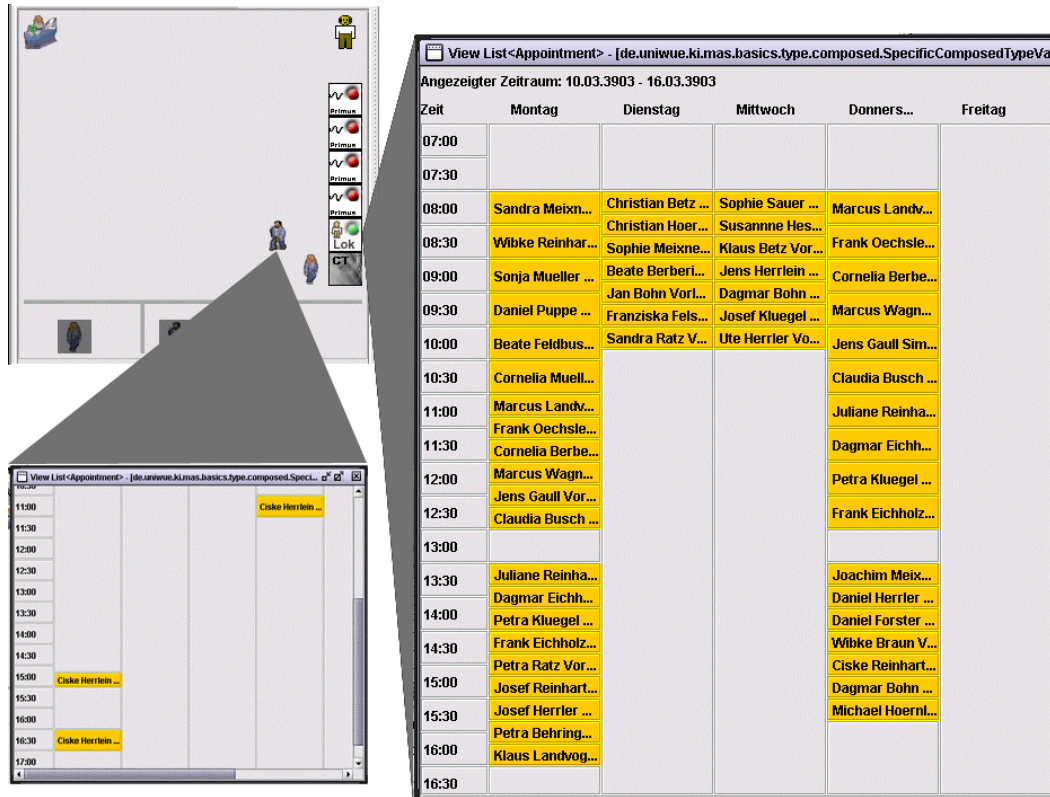


Figure 9. Weekly Schedules of Patients and Radiation Therapy Devices

On base of this model it is possible to evaluate different strategies for example first-come first-served or a preplanned schedule respecting priorities of examinations. Different hypotheses of dynamic changes (patients that come to late, additional emergencies) can be evaluated with their effects on evaluation criterions and plan stability. First experiments were able to show plausible reactions of the system. In the next step we want to model a negotiation based reactive planning system, which is supposed to be very effective in a distributed dynamic environment (Herrler et al. 2002).

Summary and Outlook

Agent technology is able to handle the high level of environmental dynamics as well as the complex and restrictive requirements of clinical trials. The aim of ADAPT is to optimize planning, management and to give decision support in the context of clinical trials. Therefore realistic simulation results are needed. So we try to extend conventional simulation, which has shown to be not sufficient (Klügl et al. 02), to a hybrid simulation system, which also includes the more flexible multi agent simulation. In multi agent modeling we have improved existing modeling techniques to handle complex models with intelligent actors. A further approach to reach the aim of realistic simulation scenarios was the integration of partial models within the Agent.Hospital initiative. FIPA compliance and consequent use of ontologies facilitate this interoperation and also enables the development of agent systems, which can be deployed from the simulation environment to an existing information system infrastructure.

System development has already come to a pretty pass. There are already demo systems which can show the possibilities of the new approaches. But indeed we still have to show practical use in the future. Ultimate aim is to bring agent systems to application. The results of simulation and developed systems can be practically used in management and control. We are now at the point,

where we soon can get results from simulation and where we can evaluate experimental agent systems and deploy them to existing information system infrastructure in the near future. Both applications (simulation/management) will be evaluated with respect to characteristic advantages of agent-based software.

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