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Semi-formal and formal specification of a telerehabilitation system for chronic respiratory diseases: methodology and feedback

Anne-Lise Courbis
Euromov DHM
Univ. Montpellier, IMT mines Ales
Ales, France
anne-lise.courbis@mines-ales.fr

Farid Arfi
Univ. Montpellier
Montpellier, France
farid.arfi@umontpellier.fr

Thomas Lambolais
Euromov DHM
Univ. Montpellier, IMT mines Ales
Ales, France
thomas.lambolais@mines-ales.fr

François Bughin
PhyMedExp
Univ. Montpellier, INSERM, CNRS, Montpellier CHRU
Montpellier, France
f-bughin@chu-montpellier.fr

Maurice Hayot
PhyMedExp
Univ. Montpellier, INSERM, CNRS, Montpellier CHRU
Montpellier, France
m-hayot@chu-montpellier.fr

Abstract—The project we are interested in involves designing and developing a smartphone application for patients participating in a clinical trial about chronic respiratory diseases, as well as a desktop application for healthcare professionals involved in monitoring the patients. This system serves a dual purpose: (i) encourage patients to follow multi-activity pathways and receive feedback; (ii) enable the care team to monitor patients' condition and notify them of milestones. In this article, we demonstrate how the main stakeholders (medical experts, physical activity specialists, nutritionists) were integrated into the requirements engineering phase, resulting in the establishment of textual specifications, UML models, and UPPAAL models. This approach has proven to be beneficial in terms of sharing knowledge, validating the telerehabilitation processes, and verifying their liveness and safety properties. Despite the stakeholders' lack of training in modelling and verification techniques, they greatly appreciated this approach.

Index Terms—requirements engineering, UML modelling, UPPAAL verification, medical processes formalisation.

I. INTRODUCTION

According to the World Health Organization (WHO), rehabilitation is a *set of interventions designed to optimize functioning and reduce disability in individuals with health conditions in interaction with their environment*. Telerehabilitation is a field of telehealth, which uses information and communication technologies to provide remote clinical rehabilitation services [16]. This article concerns the project m-Rehab which is a telerehabilitation system for patients suffering of respiratory diseases such as Obstructive Sleep Apnea (OSA). In m-Rehab, interventions are guided through a mobile application allowing several pathways to be proposed to patients supervised

by a personal team of care management which includes a care manager and experts of type care or health staff. It includes conventional functions (administrative inscription, medical information collect, GDPR, secure data server) and several specific pathways as well as video communications for therapeutic education, teleconsultings between patients and their reference doctor or their affected care manager, in order to analyse the evolution of their condition.

In this article, we focus on the requirements engineering phase which aims at collecting in the one hand the medical and care requirements, and on the other hand the system needs in order to prepare the mobile application design and development phases which are entrusted to a subcontractor. The term “specification” used in the title highlights the continuum between requirements and high level design of the solution, i.e. the specification, thanks to the model-driven approach applied during the requirements phase. Two types of models have been established: UML models (i.e. semi-formal models) to collect requirements and UPPAAL models (i.e. formal models) useful to verify processes described by experts.

In a recent work [3], we have presented a research approach pointing out the benefits of abstraction and refinement to guide the development of complex systems and illustrate the approach with the nutrition pathway of the project m-Rehab. The goal of this article is to point out the benefits of a model-based approach for all stakeholders. We illustrate the approach through a set of processes defined when a patient rises an alert. Our second goal is to share this experience with the “health community” (hospital and medical staff, software development practitioners, national and international health agencies) which must consider health and care software applications as applications requiring well-defined engineering processes including safety and liveness analyses. Indeed, the

The m-Rehab project has been supported by Occitanie region—FEDER (*Fonds Européen de Développement Régional*). Partners are laboratories: PhyMedExp (Univ. Montpellier, Fr), MRM (Univ. Montpellier, Fr), Euromov-DHM (Univ. Montpellier, IMT mines Ales, Fr), and the group KORIAN (Fr).

analysis of the state of the art presented in section II shows that few studies referring to real care or medical applications are developed through model-based and formal approaches. We present in section III the semi-formal UML approach we have followed to collect requirements. We show in section IV how the verification phase with UPPAAL has been conducted. Section V highlights the benefits of the approach. Lastly, in section VI, we will conclude and present our perspectives to make this approach effective in other health and care projects.

II. HEALTH PROCESSES MODELLING: OVERVIEW

We focus on this part on works dealing with medical processes or systems modelling to develop health and care systems. The specificity of these systems versus conventional industrial ones is the predominance of human acting (the patients and the care management team) and the definition of processes by medical staffs whose logic is about human in "face to face" and not human considered through a complex system including software, devices, data, processes and individuals with multiple skills. For example, an automatic system may be designed to give an answer within three days. However, no one can be forced to complete a questionnaire within a delay ! For these reasons, modelling is essential to discover non expected behaviour and formal verification is highly required.

There are a few works dedicated to the modelling of medical guidelines with specific languages such as Asbru [23] or GLARE [24]. More recently, a guideline meta-model has been defined [11] that is a progress for model-driven community in terms of interoperability. However, these languages are not suitable to define multiple process systems. A guideline is a support for doctors to take a decision in relation with a pathology or a diagnosis and it is generally expressed in terms of "when-then" statements. The literature survey of [25] and more recent works such as [8] point out the use of UML to represent clinical pathways. There are also a UML profile called *Healthcare Services Specification* which is dedicated to the medical domain and an international standard called *HL7 Development Framework* which aims at defining concepts for model interoperability [12]. Such modelling approaches are useful to make explicit processes and are a support for validation. However, they need to be supplemented by verification techniques to assess liveness and safety properties.

The systematic literature review of the use of formal models in medical systems performed in 2018 [7] points out that formal approaches are increasingly used in the medical field, whether for verification, validation or code generation. However, this conclusion must be mitigated because most of works are applied on the verification of critical devices such as pacemakers [14], [15] or infusion pump [4], [13] rather on medical processes. Few works refer to formal modelling to assess the proper interactions in a medical system [17], [21], other refer to the privacy and the security of data [1], [2].

Some works are closed of our approach of requirements modelling to support health software development. For instance, [5], [22] points out the benefits of Z formalism and

VDM-SL to detect specification anomalies in order to reduce development cost. [9] proposes to transform HSS models into SWN (stochastic well-formed net) to perform a Petri Net analysis. Several works are interested in model transformation to perform a formal verification. For example, in [23], Asbru models are transformed in algebraic models for the KIV prover, in [10], [19], [20], UML state machines, class diagrams, and activity diagrams are transformed into UPPAAL allowing automatic properties verification.

This overview points out that there are few works engaged in model-based and formal verification of telerehabilitation systems, despite the complexity or the criticality of such systems. The medical community has to be aware of the benefits of such approaches.

III. SEMI-FORMAL MODELLING OF M-REHAB CONTEXT AND ITS PROCESSES

UML has been chosen for several reasons: it is a standard recognised by the academic and industrial communities; several views of the same system can be modelled; it manipulates concepts common to requirements, and architectural modelling, facilitating the transition from requirements to specification, and implementation; it is compliant with the MDA (Model-Driven Architecture) facilitating models development and transformation. It should be noted that both web and mobile applications are modelled in UML because high level specifications are independant of the implementation technology.

A. The *m-Rehab context*

From the outset of the project, according to the Systems Engineering approach, the context of the project must be precisely defined in terms of organisation (consortium and the roles of each, steering and scientific committees) and the stakeholders involved at certain stages of the project's entire life cycle: funding partner, connected devices providers, software development provider, medical and care experts, application and data hosting company, representative of regulation of the healthcare sector, patients' association. This context has been modeled within Modelio environment [18] by three UML class diagrams pointing out the composition of the consortium, the steering committee and the main action delivered between the stakeholders and the m-Rehab system. These models have been greatly appreciated by the consortium and was a first simple introduction to UML that showed the benefits of graph representation.

The next steps were collecting stakeholders' requirements during a series of interviews with experts in all fields covered by the rehabilitation. Rehabilitation is an interdisciplinary process: in addition to the conventional administrative functions and patient data management, m-Rehab offers to patients three pathways: the health pathway, the nutrition pathway and the APA (Adapted Physical Activity) pathway. It implies that requirements have been expressed by several experts coming from a variety of backgrounds (lung specialists, nutritionists, APA specialists) in a very challenging context for developing

a preponderant software system: experts do not share the same vocabulary; they do not have a precise knowledge of other specialities pathway; they collaborate to define a new profession, the care manager, who is not represented by a stakeholder but co-constructed by experts who defined what actions are expected from his role during the rehabilitation pathways under definition. The challenge of this project was to collect requirements and make them traceable and shareable between all experts in an easy-to-read format and to be able to discover the duties assigned to the care manager.

We will not explain these pathways in detail but summarise their common features. Each pathway has therapeutic education materials and asks patients to carry out activities according to a personalised program. Every activity is evaluated and an automatic feedback is delivered to patients in order to motivate them. Data are collected all along the different pathways through connected devices, physiological tests or questionnaires. Synthetic views of data evolution are presented according to various temporal scale (week, month, semester) both to patients and their team of care management. The processes involved in each pathway were initially defined in text form by transcribing the interviews. Class diagrams were drawn up and shared with all the experts all along the project in order to highlight the concepts. Class diagrams were supports to make synthesis of the progress of work, and verify if stakeholders' requests were clearly understood. They have also made it possible to draw up a dictionary of terms so that all stakeholders share the same unambiguous vocabulary. Fig. 1 is an excerpt of a UML class diagram pointing out some basic concepts of m-Rehab project and their relationships.

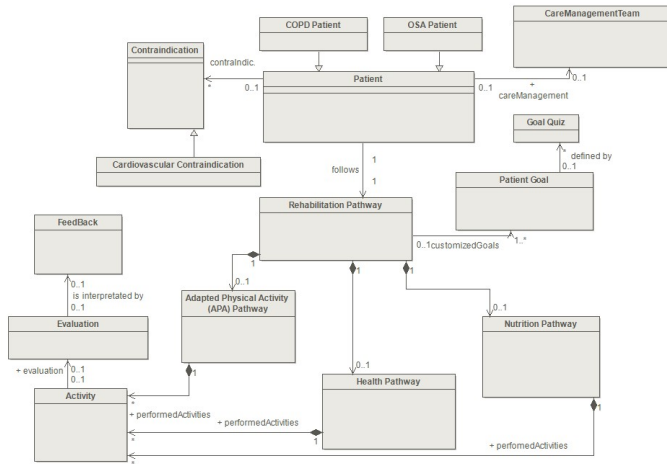


Fig. 1. Class diagrams pointing out some concepts of m-Rehab (excerpt)

We are going to look at the alert process, belonging to the health pathway, in order to illustrate the UML modelling of a process and its formal modelling for verification purposes.

B. The patient alert management process defined in natural language

We focus in this section on a process defined by health experts in order to clarify what is expected when a patient

suffering of OSA triggers an alert. It should be noted that patients have been trained and are familiar with their condition. In the event of emergency, they should go to hospital or call the emergency services. The alarm is triggered when the patient experiences problems with the respiratory device for continuous positive airway pressure (CPAP).

This process is interesting because it involves several health-care professions that need to be synchronized and informed of expected actions that have or have not been carried out. A sub-process of m-Rehab is responsible of this synchronisation and knowledge sharing. It will be called HealthAlert in the remainder of this document. These professionals are: a home-care personnel (HCP) who is in charge of the CPAP device at the patient's (P) home, the care manager (CM) and in some case, the patient's doctor (Dr). The process initially described by health experts is as follows:

When the alert is triggered, the CM and the HCP are informed by receiving a notification. The HCP usually arrives at the patient's home within three days. Consequently, three days after the alert, the mRehab system should ask the patient whether the HCP's actions have improved his/her condition. If so, the alert is automatically closed. If not, the condition is evaluated every two days, for a maximum 10 day period, until it is stabilised. If the condition fails to stabilise, the Dr receives a notification on his dashboard, the CM communicates with the patient and acts in relation to the Dr's advice.

C. UML modelling of the patient alert management process

This first specification was considered "right" by the health experts but from the requirements engineer it has to be correct, complete, consistent and unambiguous. It immediately appears that the specification is incomplete since some cases are not covered, for instance: (Q1) what happens if the HCP does not intervene at the patient's home? (Q2) how does the system know that the HCP has intervened? In order to address these issues, another interview has been organised based on the modelling of the process in the form of UML sequence diagram (cf. Fig. 2). The five vertical lines of this diagram represent the five roles (or processes) involved in the alert management: P, HealthAlert, HCP, CM and Dr. The advantage of this diagram is to enable health experts to see the different cases, to be able to "play" the scenarios with the help of the modeller, and to complete the specification for uncovered cases. Sometimes, it could be difficult to address some issues. The answer of experts to Q1 was: it is impossible for the HCP not to come. But for an automatic system, such a case has to be foreseen! Nevertheless, a specification may be correct and complete (that was not our case even after some corrections), but not consistent, and ambiguous. This is why we have transformed the process into a formal model and defined expected properties in conjunction with the health experts.

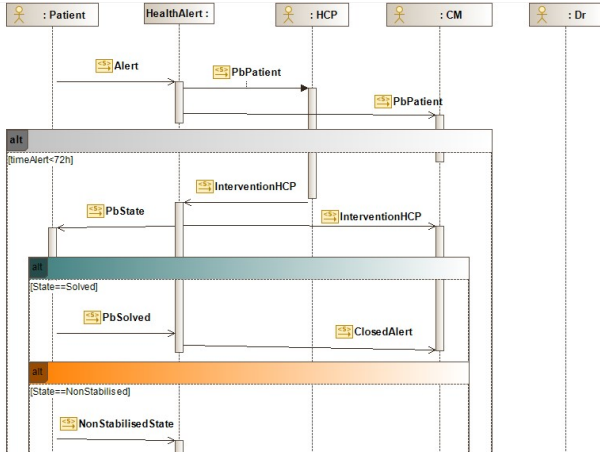


Fig. 2. UML Sequence diagram highlighting the patient alert management process(excerpt)

IV. FORMAL MODELLING AND VERIFICATION OF THE PATIENT ALERT MANAGEMENT PROCESS

The step of formal verification is performed using the UPPAAL language and its associated model checker [6] allowing models to be expressed as timed automata. Three reasons have motivated this choice: (1) UPPAAL tool is appropriate to verify both liveness and safety properties; (2) UPPAAL has often been applied in the medical field, it has long been used for industrial systems and we are confident in its efficiency; furthermore, its simulation tool is appropriate to explain to non experts why a given property is not verified; (3) there are many timed constraints in the m-Rehab specification and this aspect is taken into account by the language and the verification tool.

A. Property expression in natural language

After modelling the patient alert management process, we have discussed with health experts in order to define some expected properties. It should be noted that health experts are not able to express alone these properties and a question/answer interview has been necessary. From this discussion, we have stated five properties (see Table I).

TABLE I

EXPECTED PROPERTIES FOR THE PATIENT ALERT MANAGEMENT PROCESS

Ref.	Property expression
P_1	The alert management process has no dead lock.
P_2	Dr. does not receive a notification if the alert has been treated by the HCP.
P_3	Any alert will eventually be closed.
P_4	After the alert, P is guaranteed to receive an intervention from HCP or Dr. within four days maximum.
P_5	Despite a HCP intervention, patient's issue may not be solved.

B. Formal modelling of the alert process with timed automata

The alert process represented in Fig. 2 as a sequence of interactions has been modelled in UPPAAL (cf. Fig. 3) as five collaborating processes, each of them corresponding to a specific role. The main process is naturally the alert management

by the m-Rehab system (process HealthAlert). Other ones correspond to possible human interactions with the m-Rehab dashboard. For instance, when the patient rises an alert (Alert! in Patient), it is synchronised with the HealthAlert process (Alert?) and it is propagated to the CM and the HCP processes (PbPatient!). It should be noted that the HCP intervention is represented in the HCP process by a transition labelled with a synchronisation on channel InterventionHCP!. Another transition on this process represents the fact that the HCP did not intervene after 3 days ($x < 3$ invariant). This enable to complete the textual specification, taking into account that the HCP may not intervene. However, the UPPAAL modeler didn't correct other processes in order to highlight a possible problem.

C. Property expression in UPPAAL

The UPPAAL model being established, properties expressed in Table I can be formalised using a subset of the TCTL (Timed Computation Tree Logic), by referring to specific operator, the states name of the automata, as well as variables and clocks. ϕ et ψ being two propositional calculus formula, notations $A\Box\phi$, $E\Diamond\phi$ and $\phi \longrightarrow \psi$ respectively represent that ϕ is always true, there exists a branch leading to set up ϕ to true, and in any situation, ϕ being true will lead ψ to true. For a complete explanation of UPPAAL logic, see [6]. Table II gives the corresponding UPPAAL expressions of properties defined in Table I.

TABLE II

EXPECTED PROPERTIES FOR THE PATIENT ALERT MANAGEMENT PROCESS

Ref.	Property expression in UPPAAL
P_1	$A\Box$ not deadlock.
P_2	$A\Box$ HCP.SolveIssue imply !Dr.ReceivedNotification.
P_3	Patient.AlertOn \longrightarrow !Patient.AlertOn.
P_4	HealthAlert.ReceivedAlert \longrightarrow Intervention && $x \leq 4$.
P_5	$E\Diamond$ Intervention && !State == Solved.

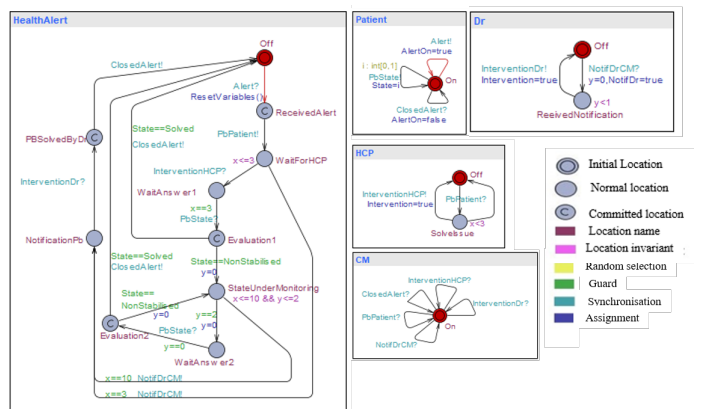


Fig. 3. Patient alert management expressed by timed automata.

D. Property verification

Properties are submitted to the UPPAAL model checker: all of them are verified, except properties P_1 and P_3 because

the system alert management has been designed under the hypothesis that the patient will necessarily complete the questionnaire within 3 days of the alert being triggered, that is not realistic. The synchronisation of his/her answer is possible only in the 3 days, leading to a HealthAlert process waiting for a non possible synchronisation. The same reasoning was applied to the patient monitoring if his/her condition did not improve after the HCP visit. This issue has been discussed with health expert to define what is expected, without any support of formal modelling, but with the UML support. It has been decided that 2 extra days are granted to the patient to answer the questionnaire: the formal model as well as the textual specification have been accordingly modified. Nevertheless, with this correction, property P_1 is still not verified and UPPAAL model checker gives a counter-example (see Fig. 4). Indeed, there is a deadlock on the m-Rehab process since without answer of the patient in the target time interval, the system can no longer evolve. We have again discussed with health experts by simulating step by step the UPPAAL counter-example. They decided to assign a new task to the CM to handle this situation: a notification will be sent to the CM who have to contact the patient, manually close the alert, and depending on his/her condition, ask the patient to rise a new alert to restart the process. The textual description has been again modified as well as the formal model (Fig.5): two transitions have been added to force the system to exit the state waiting for patients' answer and to synchronise with the CM: by this way, there is no more deadlock, and all properties are verified.

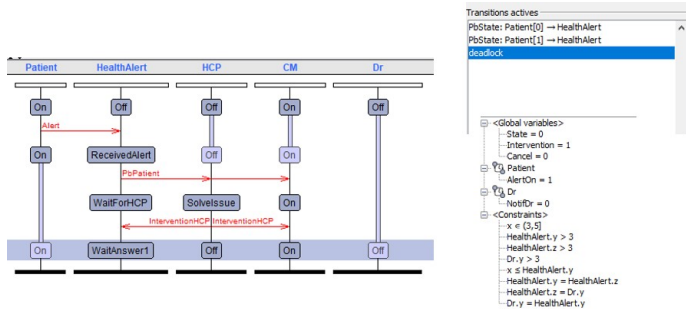


Fig. 4. Counter-example generated by UPPAAL pointing out that P_1 is not verified.

The same approach has been applied on processes requiring synchronisation and the sending of notification between m-Rehab processes and the dashboard of the CM or Dr. Setting up UPPAAL models and checking expected properties have been a support to target problems, simulated them with non experts in formal modelling. By this way, we increase our confidence in having correct, complete, consistent and non ambiguous specification, before delivering them to the development team.

V. M-REHAB EXPERIENCE FEEDBACK

The m-Rehab specifications were drawn up over 18 months, because of the complexity of processes, the diversity of stakeholders and their availability (they are practitioners in

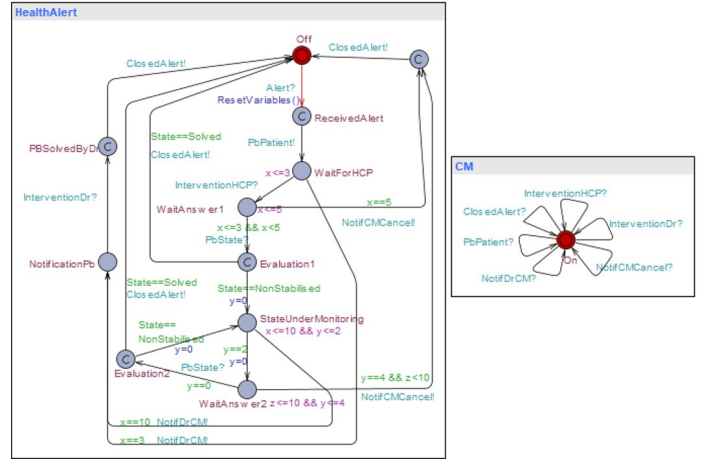


Fig. 5. Correction of HealthAlert and CM processes represented in Fig. 3.

a hospital). A lot of interviews and corrections have been required, both on textual specification and UML models. The final deliverable consists of documents totalling around 600 pages, a unified model counting about 300 classes, 10 dynamical descriptions, and a dictionary of 70 terms.

Given the large number of requirements and the complexity of the rehabilitation pathways, a semi-formal modelling approach was needed first. It would not have been possible to start with formal modelling. The UML modelling approach makes domain expertise tangible, so that it can be refined and corrected through collaboration between designers and experts. The final specification is thus clearer and more precise than a purely textual document. Overall, UML has made it possible to achieve the following objectives:

- share concepts that were not common to all stakeholders at the start of the project;
- have a tangible basis to define, discuss, correct and refine the requirements, each stakeholder being able to see his/here high-level processes;
- provide an overview of the functions associated with the care manager, thanks to the cross-functional view of all the processes in which it is involved.
- give to project leaders and software development team both a detailed view of the telerehabilitation system but also a cross-functional view about common concepts such as notification, agenda, synchronisation etc.
- adopt a modular organisation and then implement an incremental and iterative development approach. This made it possible to work on part of the specifications without necessarily knowing the whole. This process reduces the cost and complexity of modelling.
- participate to test the pre-production software with an expertise on critical parts.

More surprisingly, formal modelling has not been a strict barrier: UPPAAL's simulations and counter-examples have made concepts that are difficult for non-experts in temporal logic to grasp. UPPAAL's graphical models were appreciated for demonstrating deadlocks or unsatisfied properties. They were appreciated because they made it possible to identify

errors that had remained hidden. On the other hand, we note that, even informally, it was difficult to get the experts to state properties: even if these properties correspond to requirements, the experts do not reason in these terms but rather describe their know-how. This experience has highlighted the need to combine semi-formal and formal models in order to define validated processes. Finally, having a tangible support in the form of a model was very useful for discussions and for reassuring all stakeholders about the state of progress of the project. It should be noted that the automatic transformation of UML into UPPAAL was not planned as part of the project. It is currently being developed in order to be able to generalise the approach to other telerehabilitation systems.

VI. CONCLUSION AND FUTURE WORK

This experiment of requirements engineering through a model-based approach on a real telerehabilitation system has been challenging and of great interest, specially to analyze the stakeholders' feedback. According to the WHO, non communicable diseases (NCDs), are the leading cause of death worldwide [26]. One of its program named Global NCD Compact 2020–2030 aims to accelerate progress on the prevention and control of NCDs. As a result, telerehabilitation systems will increasingly be used. Our experience may be capitalised and generalised by defining a meta-model of telerehabilitation from concepts defined in m-Rehab. Our future work will focus on developing a modelling tool that will enable medical staff, assisted by a requirements engineer, to describe the context and the system they would like to obtain for a given pathology, and to automatically transform the models into UPPAAL.

Lastly, companies of ICT and health sectors need to be made aware of the relevance of the model-based approach at the early stage of a project development and the use of formal approaches to develop reliable systems.

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