



IMT Mines Alès
École Mines-Télécom



APPLYING MDE & FORMAL VERIFICATION TO SPECIFY A TELEREHABILITATION SYSTEM: METHODOLOGY & FEEDBACK.

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1. CONTEXT OF THE STUDY

M-Rehab Project





m-Rehab:

- Project for developing a **clinical trial** for patients suffering of chronic respiratory diseases (COPD*, OSA**)
- **Telerehabilitation system** for “connecting” patients and health professionals
- Patients may have **rehabilitation in specialized center**, but forget good habits
- This type of diseases requires **regular monitoring** and a **healthy lifestyle**

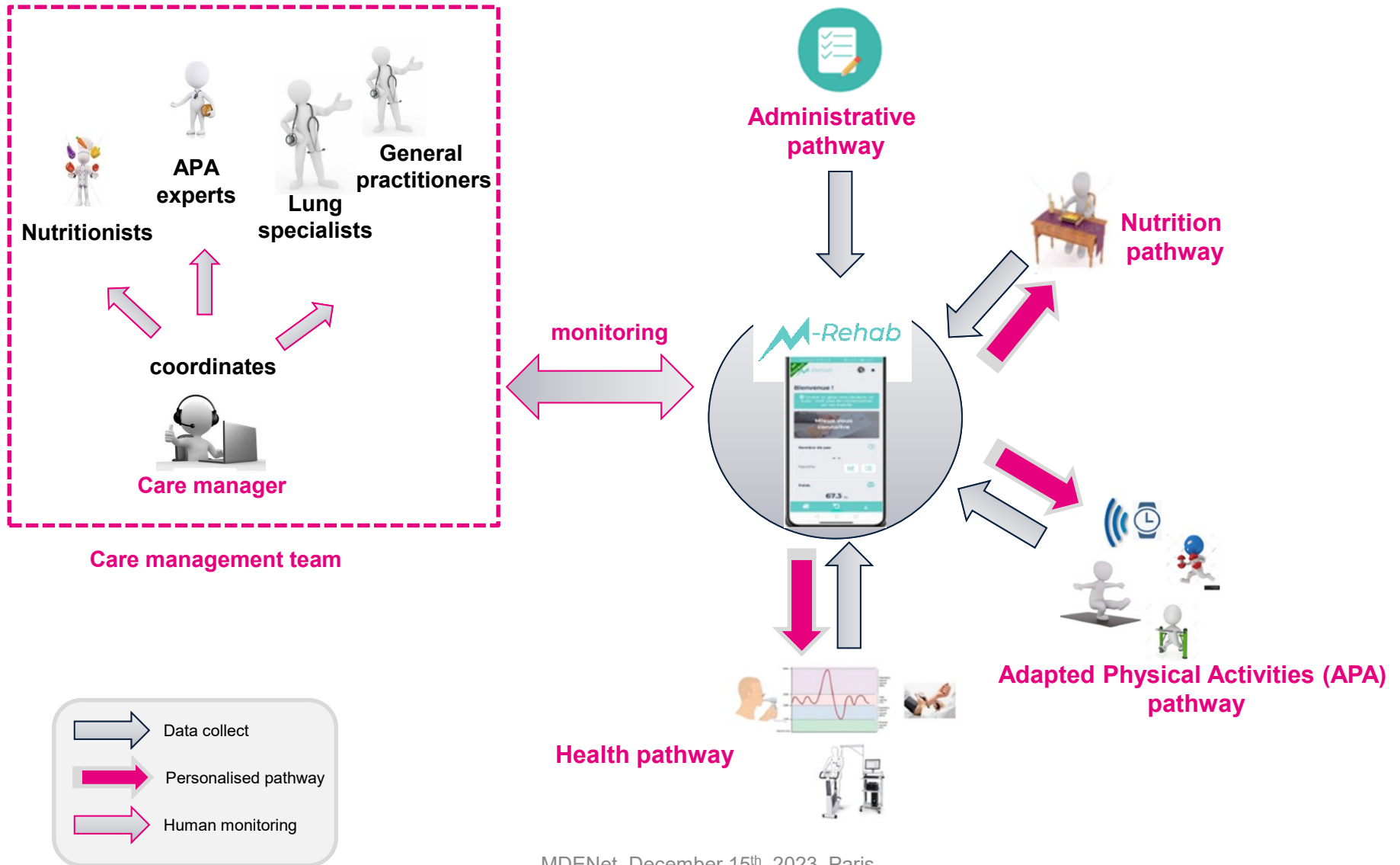
**COPD: Chronic Obstructive Pulmonary Disease*

*** OSA: Obstructive Sleep Apnea*

[1] WHO – World Health Organization

1. CONTEXT

1.1 The m-Rehab project: many processes to monitor patients



Main features of the system under study:

- ▶ **Many processes:** administrative, health, nutrition, APA
 - Stakeholders have their own expertise for one process, but no one has the complete view of the system
 - There are many interactions: patients/professionals & devices/m-Rehab
 - Time scales depend on the field of processes: every month for weight control, every day for APA.
- ▶ **Processes are interdependent**
 - Many synchronisations inside a pathway
 - Many communications between pathways
- ▶ Many **human actions** are expected through m-Rehab
- ▶ The system is monitoring **patients: reliability** is a important feature, design approach may be conducted by **verification processes**

No one has an exhaustive view of patients' pathways

Every one is expecting actions from a new role, i.e. the care manager

OUTLINE

1. CONTEXT

- 1.1 The mRehab Project
- 1.2 Multi disciplinary requirements
- 1.3 System Engineering approach

2. SETTING UP MODELS

- 2.1 From interviews to UML models
- 2.2 Models as supports for requirements reviews
- 2.3 Stakeholders' feedback

3. FORMAL MODELING

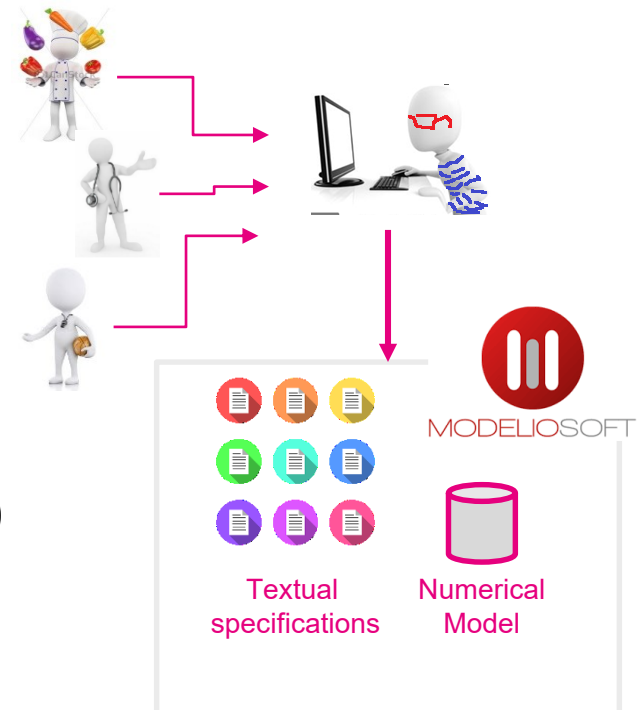
- 3.1 Rationale of the study
- 3.2 UPPAAL modeling
- 3.3 Properties verification
- 3.4 Stakeholders' feedback

4. CONCLUSION & PERSPECTIVES



Experts' requirements elicitation:

- ▶ Interviews with experts:
 - What is expected by the project leaders (general goals of m-Rehab)
 - For each pathway (Nutrition, APA, Health, Administration), definition of:
 - **Sub-pathways** and procedure to select the appropriate one
 - **activities**, collected data and automatic **feedback** to be generated
 - **progression** into a pathway
 - Patients' **markers** for the dash board
- ▶ Using:
 - **Iterative interviews** based on **textual** specifications & **diagrams**
 - Misunderstanding / error **tracking** & **corrections**
- ▶ During:
 - 18 months to complete all pathways (150 days)

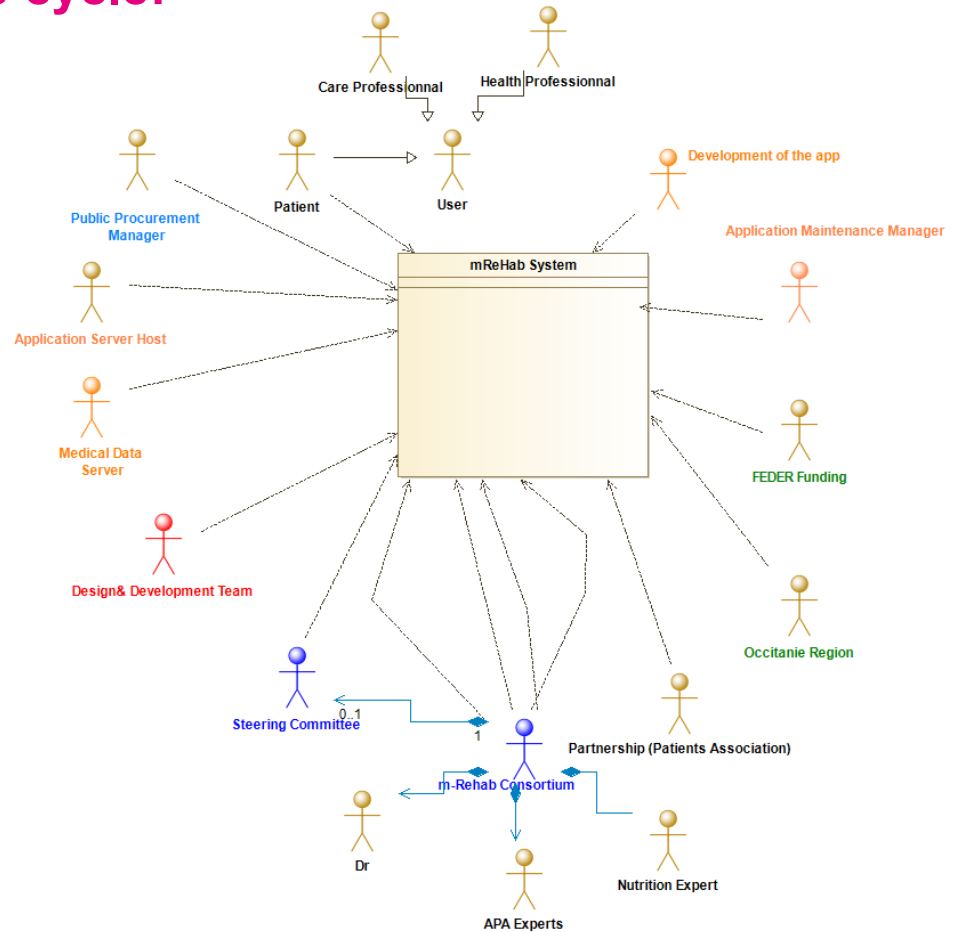


m-Rehab context through its life cycle:

- ▶ Overview of stakeholders
- ▶ Overview of responsibilities
- ▶ Glossary

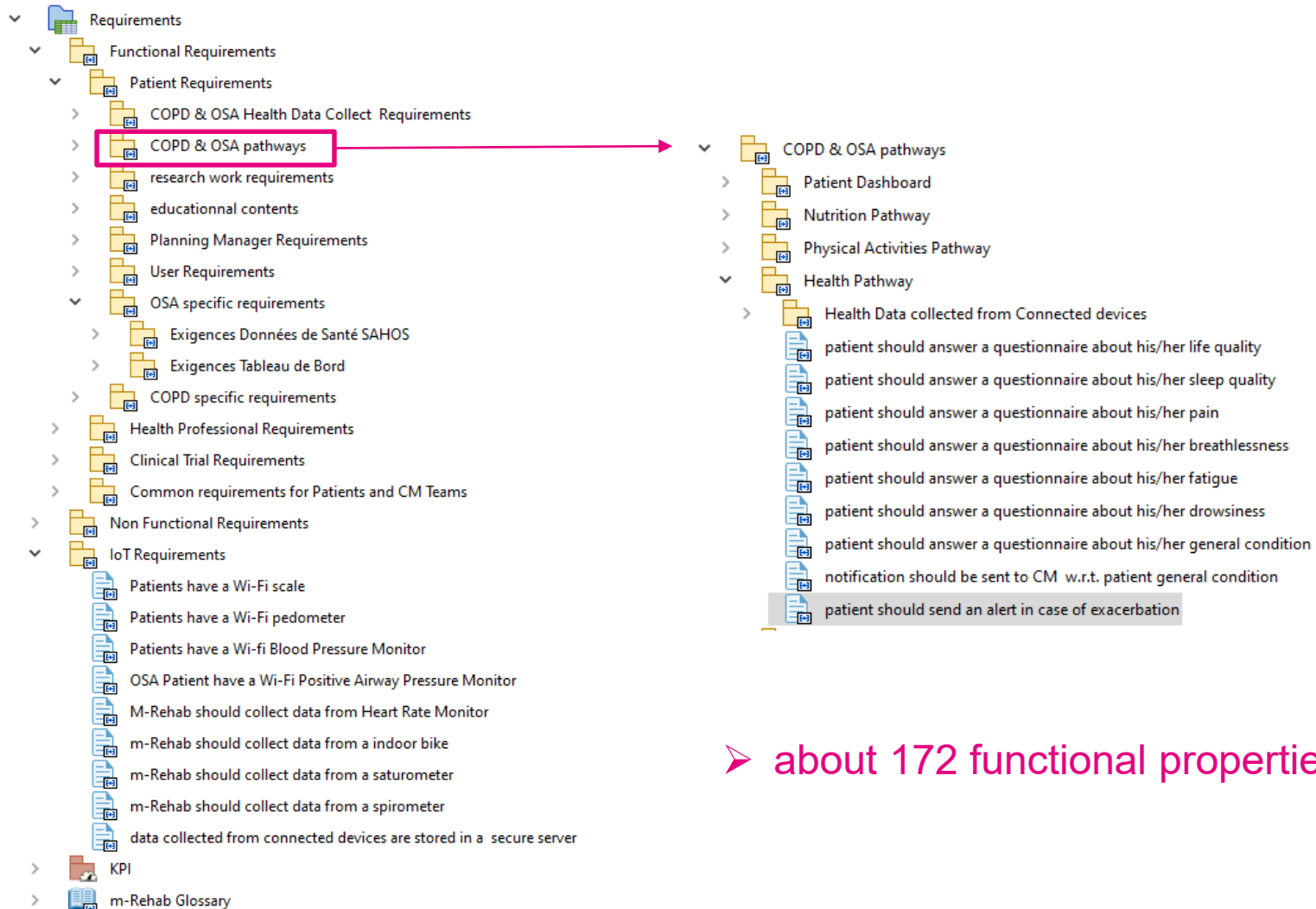
- ▼ Termes Pour les Essais Cliniques
 - Case Report Form (CRF)
 - Direction Recherche Clinique (DRC)
 - Comité de Protection des Personnes (CPP)
 - Promoteur
 - Essai Clinique
 - Comité de Surveillance et de Suivi (CSS)
 - Protocole
 - Centre Investigateur
 - Investigateur
- ▼ Termes de l'usabilité des applications
 - Adaptabilité
 - Actions Explicites
 - Actions Minimales
 - Brièveté
 - Charge de Travail
 - Compatibilité
 - Concision
 - Contrôle Explicite
 - Contrôle Utilisateur
 - Correction des Erreurs
 - Densité Informationnelle
 - Feedback Immédiat
 - Flexibilité
 - Gestion des Erreurs
 - Guidance

▶ 90 terms



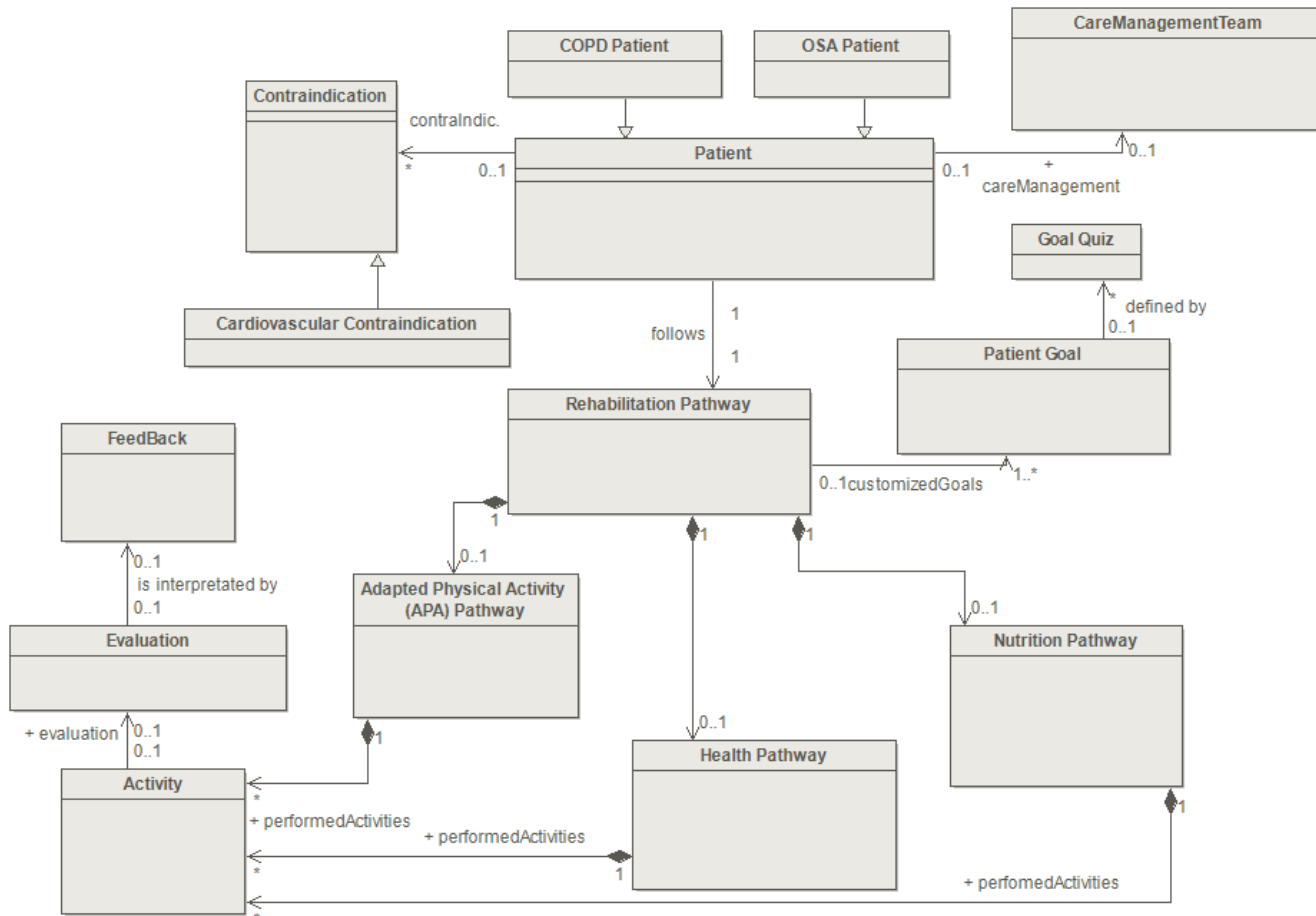
▶ more than 15 stakeholders

Requirements elicitation:

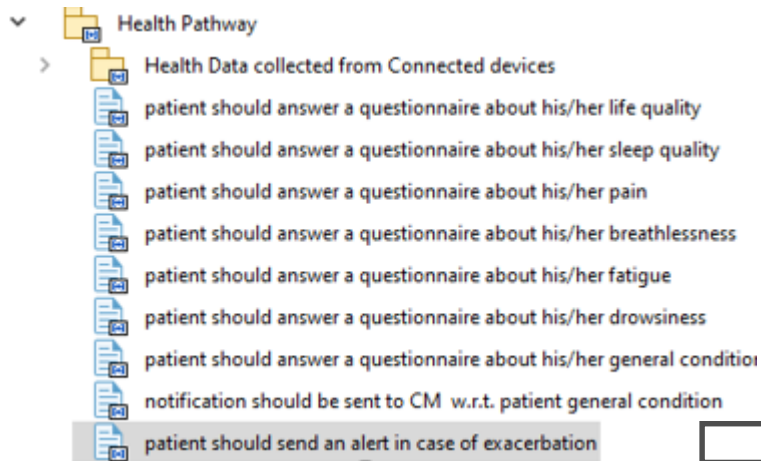


➤ about 172 functional properties

Modeling of concepts extracted from requirements:



Modeling of processes from specification (detailed requirements):



When the *alert is triggered*, the CM and the HCP are receive a notification. The *HCP usually arrives at the patient's home within three days*.

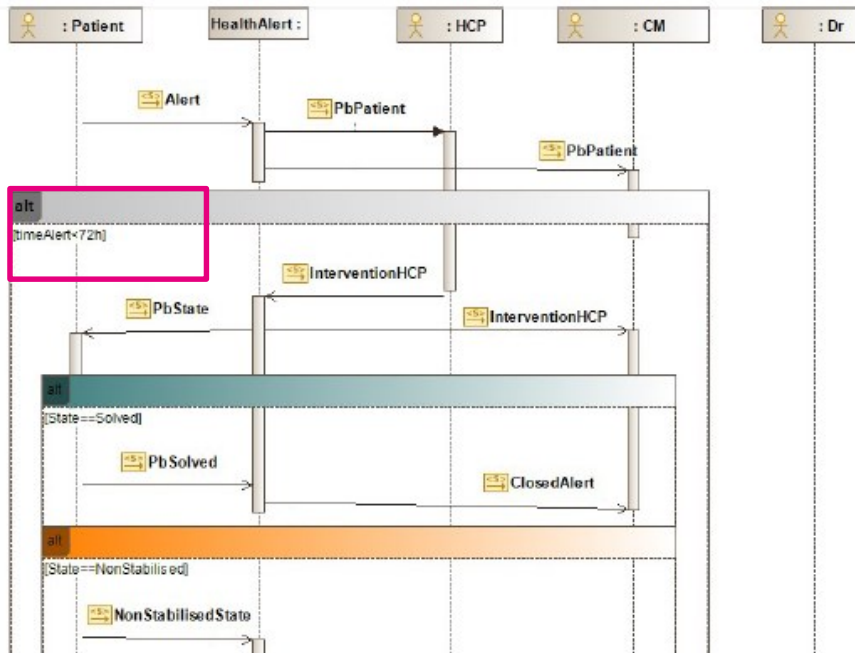
Consequently, three days after the alert, the mRehab system should ask the patient whether the HCP's actions have *improved his/her condition*. If so, the *alert is automatically closed*. If not, the *question is asked every two days* until the patient's condition has stabilised, for a *maximum 10 day period*. At the end of 10 days, *if the condition is stabilised*, the Dr receives a notification on his dashboard, the CM communicates with the patient and acts in relation to the Dr's advice.

CM : care manager
HCP: home care person
Dr : doctor, medical staff

➤ Is this specification:

- complete?
- consistent?
- unambiguous?

Modeling of processes from specification (detailed requirements):



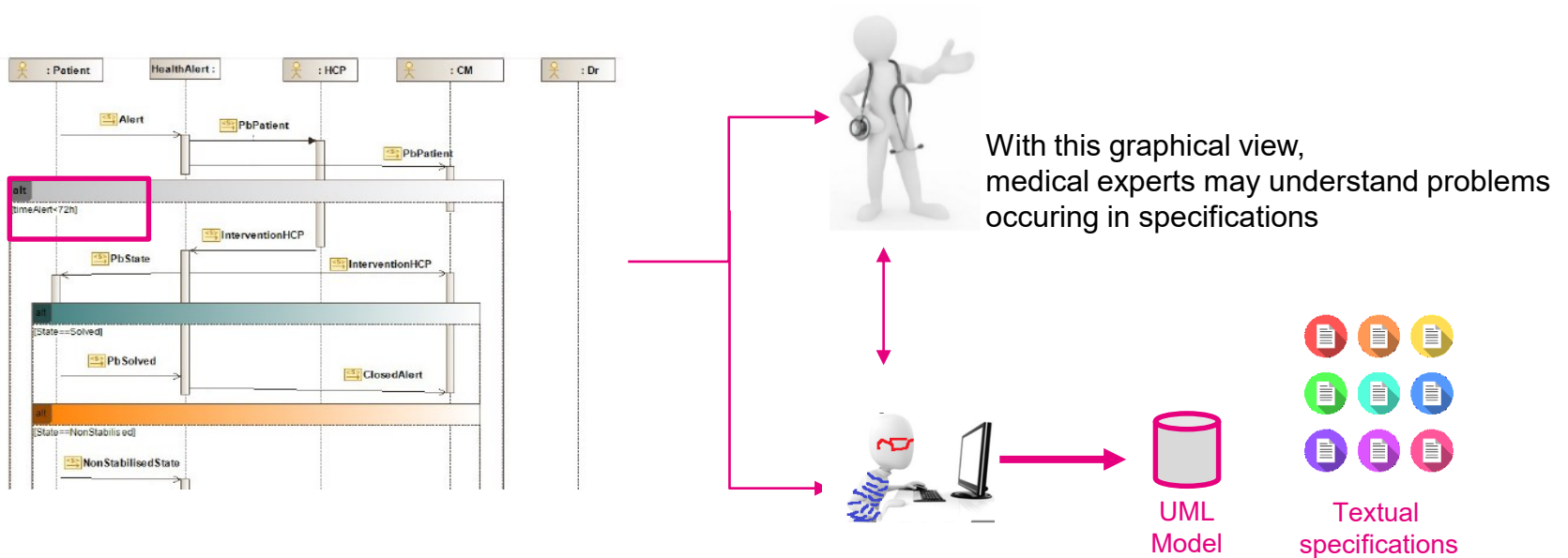
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CM : care manager
HCP: home care person
Dr : doctor, medical staff

➤ **The specification does not define:**

- what is expected if Intervention of HCP is not occurring
- what is expected if patient's condition is not stable after 10 days

Modeling of processes from specification (detailed requirements):



Advantages of UML modeling:

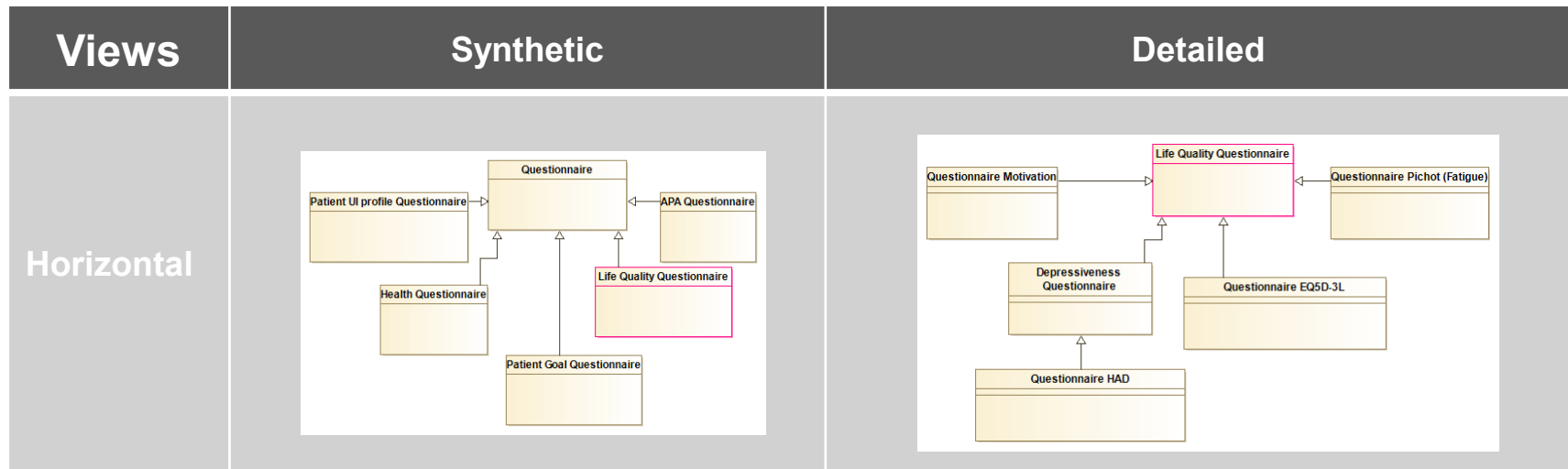
- Formalism that stakeholders appreciated, even if they have not be trained
- Graphical view makes specifications easier to read, discuss and correct
- It is appropriate to apply System Engineering approach: unique model allowing knowledge to be shared, modified and traced.
- Good support to validate specifications with all stakeholders
- Synthetic views vs detailed views of processes that nobody knows entirely
 - Horizontal View (per concepts)
 - Vertical View (per expertises)



Textual Specifications
(30 files of specification)



UML Model
(340 classes and 10 processes)



2. SEMI FORMAL MODELING

2.3 Stakeholders' feedback

Advantages of UML modeling:

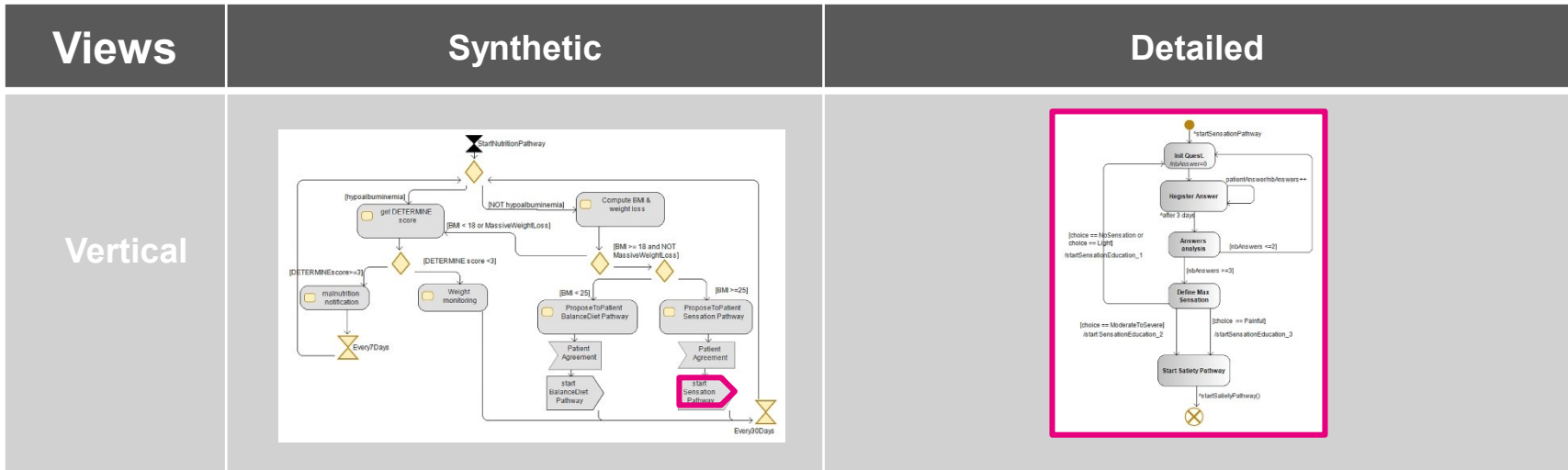
- Formalism that **stakeholders appreciated**, even if they have not be trained
- Graphical view makes **specifications** easier to read, discuss and **correct**
- It is appropriate to apply System Engineering approach: **unique model** allowing knowledge to be shared, modified and traced.
- Good support to **validate** specifications with all stakeholders
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 - Horizontal View (per concepts)
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Textual Specifications
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UML Model
(340 classes and 10 processes)



Disadvantages of UML modeling:

- Modeling may **appear as time consuming**. However, obtaining **validated specifications** saves a lot of development **time and money**
- UML have several semantic variation points
- UML is **not appropriate to formal verification** (i.e. demonstrate expected properties of processes)
 - What about the liveness of processes ?
 - Are processes deadlock free ?
 - Do the processes have the properties set out by the experts?
 - Do the processes interactions conform to specifications ?

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4. CONCLUSION & PERSPECTIVES



3.1 Rationales of the study

Observation:

- ▶ Health / Care applications may be considered as **critical applications**
- ▶ Design and development of such applications must be conducted by the use of :
 - **proven methodologies**
 - **validation & verification procedures**

Astonishment:

- ▶ The state of the art concerning Health / Care applications does not highlight these expected features [1]. Formal methods are usely applied:
 - for **medical devices** (pacemakers, infusion pump)
 - for **single-process medical guidelines**

[1] Bonfanti S, Gargantini A, Mashkoor A. A systematic literature review of the use of formal methods in medical software systems. *Journal of Software: Evolution and Process*. 2018;30(5):e1943.

3.2 UPPAAL model

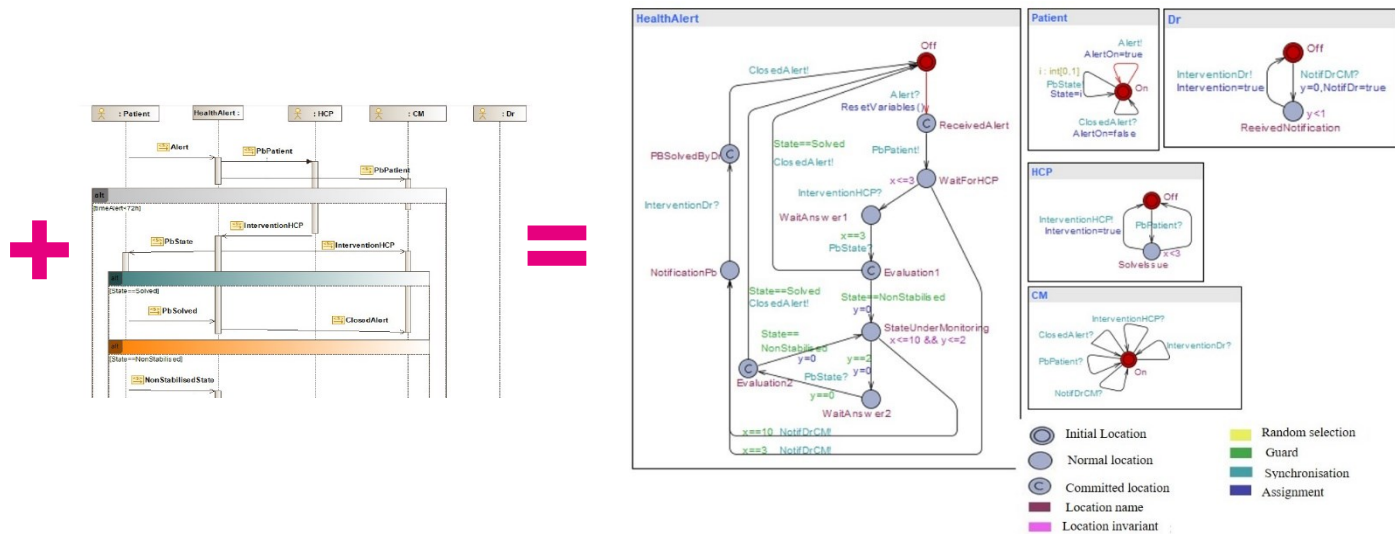
UPPAAL properties:

- ▶ Based on TCTL logic ; it is appropriate for modelling & verifying both liveness and safety properties
- ▶ Timed constraints are handled by the language
- ▶ Its efficiency is demonstrated by the state of the art
- ▶ Both textual and graphical representations are available;
- ▶ Counter-examples are produced to highlight problems

From UML to UPPAAL models

- ▶ The transformation may be automated (not done during this project)

When the alert is triggered, the CM and the HCP are informed: the HCP and the CM receives 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 question is asked every two days until the patient's condition has stabilised, for a maximum 10 day period. At the end of 10 days, if the condition is stabilised, the Dr receives a notification on his dashboard, the CM communicates with the patient and acts in relation to the Dr's advice.

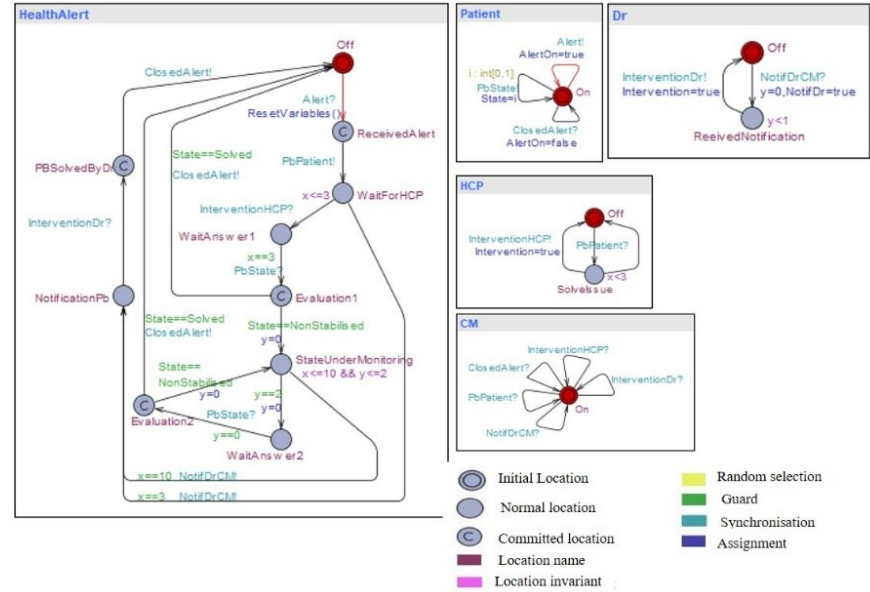


Properties defined through interviews with experts:



Properties elicitation

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	Some interventions may solve the patient alert.
P_6	Despite a HCP intervention, patient's issue may not be solved.



UPPAAL properties transformation

Ref.	Property expression in UPPAAL
P_1	$A \Box \text{not deadlock.}$
P_2	$A \Box \text{HCP.SolveIssue imply !Dr.ReceivedNotification.}$
P_3	$\text{Patient.AlertOn} \rightarrow \text{!Patient.AlertOn.}$
P_4	$\text{HealthAlert.ReceivedAlert} \rightarrow \text{Intervention} \ \&\& \ x \leq 4.$
P_5	$E \Diamond \text{Intervention} \ \&\& \ \text{State} == \text{Solved.}$
P_6	$E \Diamond \text{Intervention} \ \&\& \ \text{!State} == \text{Solved.}$

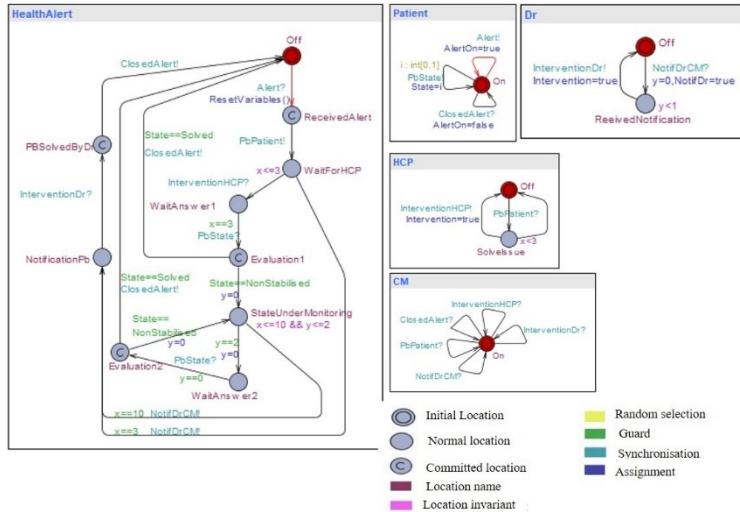
$A \Box \phi$, ϕ is always true

$E \Diamond \phi$ ϕ may be true

$\phi \rightarrow \psi$ ϕ being true will lead ψ to true

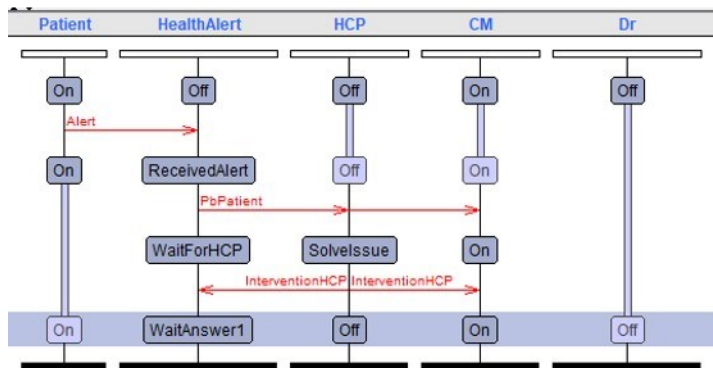
3. FORMAL MODELING

3.3 Properties verification



Ref.	Property expression in UPPAAL
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Counter-example: P1 has a dead-lock



Transitions actives

```

PbState: Patient[0] → HealthAlert
PbState: Patient[1] → HealthAlert
deadlock:

```

```

<Global variables>
- State = 0
- Intervention = 1
- Cancel = 0
Patient
- AlertOn = 1
Dr
- NotifDr = 0
<Constraints>
- x ∈ (3,5]
- HealthAlert.y > 3
- HealthAlert.z > 3
- Dr.y > 3
- x ≤ HealthAlert.y
- HealthAlert.y = HealthAlert.z
- HealthAlert.z = Dr.y
- Dr.y = HealthAlert.y

```

HCP comes to see Patient at day 3: Patient didn't have any delay to answer the questionnaire about his/her condition....No complementary scenario to deal with this problem has been defined.

3. FORMAL MODELING

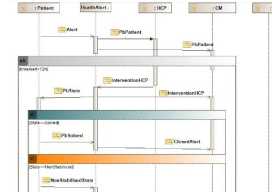
3.3 Properties verification



Modification of the specification : *if the patient didn't answer about his/her condition after 5 days, the care manager has to be informed and the alert is automatically closed.*

➔ Modification of the UML model:

Complete the sequence diagram....

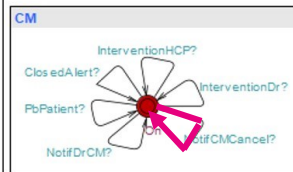
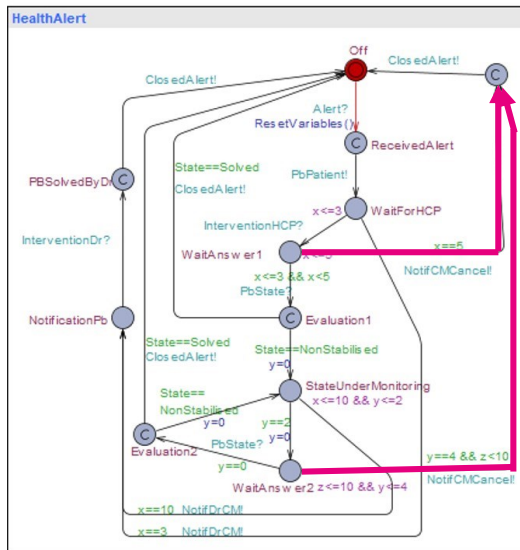


➔ Modification of the properties

according to new specification:

After the alert, P is guaranteed to receive an intervention from HCP or Dr. within four days maximum.

➔ Modification of the UPPAAL model



Ref.	Property expression in UPPAAL
P_1	$A \square$ not deadlock.
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P_4	HealthAlert.ReceivedAlert \rightarrow Intervention && $x \leq 4$.
P_5	$E \diamond$ Intervention && State == Solved.
P_6	$E \diamond$ Intervention && !State == Solved.



Advantages of formal modeling and UPPAL:

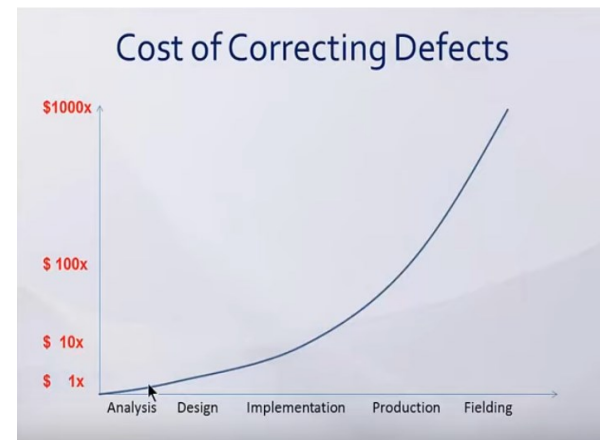
- ▶ Deep analysis of the specification for setting up models.
- ▶ Deep analysis and discussions with stakeholders for defining expected properties (both detailed work and synthetic view / stepping back is necessary).
- ▶ Highlighting and simulating a counter-example allows the problem to be understood and the corresponding scenario to be explained to stakeholders.
- ▶ Increase the confidence into specifications before/during development of the software.

Disadvantages of formal modeling:

- ▶ An **expertise** in formal modeling is required: difficulties in hiring young engineers or researchers in this field.

- ▶ It is **time consuming** (apparently !)

- ▶ **Corrections** have to be made both in **textual specifications** and **UML models**



Source: W. B. Smith. Characteristics of MBSE, Vitech Corp. 2013

- ▶ Defining **expected properties of processes** is difficult for medical experts

- ▶ **Stakeholders are not attracted** by formal approaches and do not understand their benefits (even the development team !)

4. CONCLUSION & PERSPECTIVES

Lessons learned from this experience:

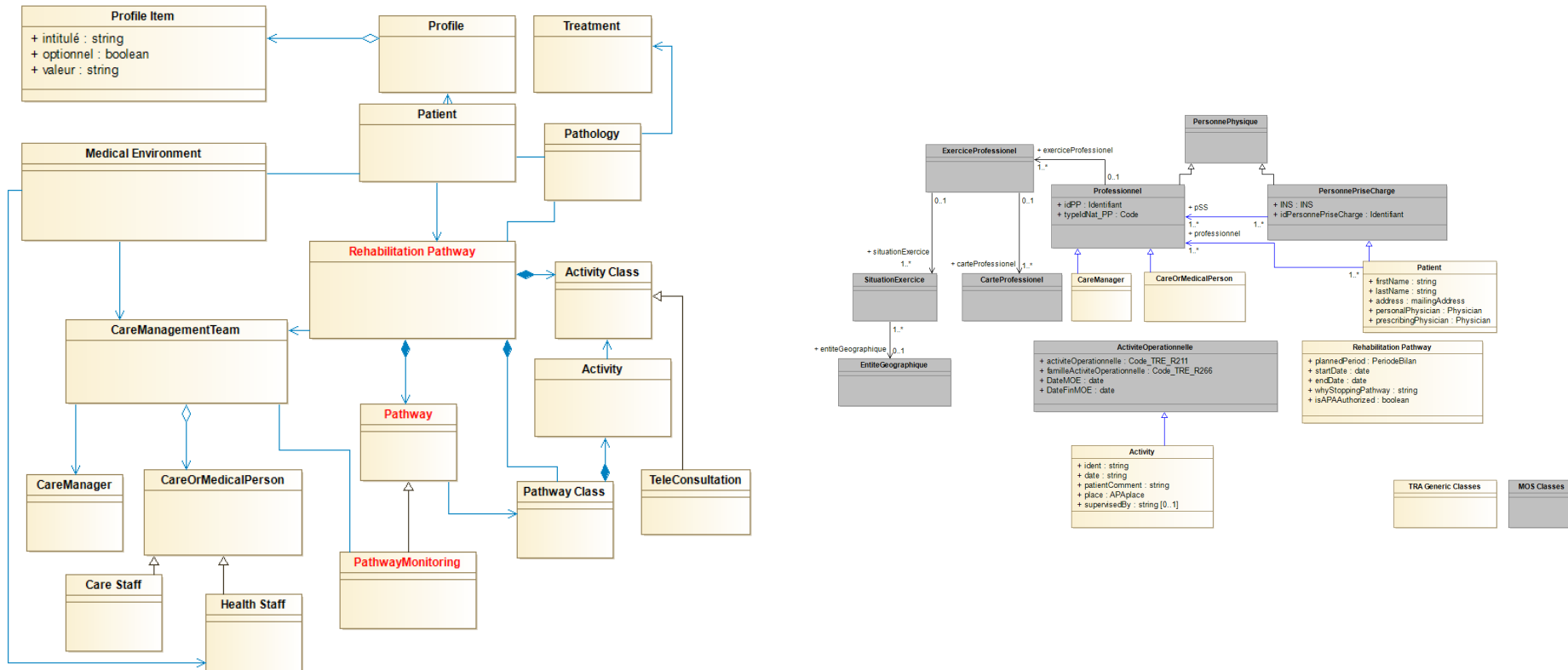
- ▶ **Great challenge** to collect requirements for a care & health application
 - Medical / Hospital staff are very busy.
 - Their knowledge is based on face-to-face with patients (who always answer to their questions...).
 - Time for validating and correcting specifications is short.
- ▶ **Graphical modeling is a real support** for requirements & needs collect
- ▶ The **incremental MBSE** [2] approach needs to be **more widely used**
 - for requirement analysis
 - for software design
 - for software implementation
- ▶ **Testing** such applications is difficult because scenarios have to be played over 3 days, 1 week (e.g. APA), several month (e.g. APA, denutrition)...

[2] Formal Verification of a Telerehabilitation System Using Abstraction & Refinement, F. Arfi, AL. Courbis, T. Lambolais, F. Bughin, M. Hayot, IET Software, 2023.

Work in progress:

► Capitalization of the experience

- Definition of a **meta-model** for TeleRehabilitation Applications (TRA) **compliant** national (MOS in France) or international standards (fHIR)

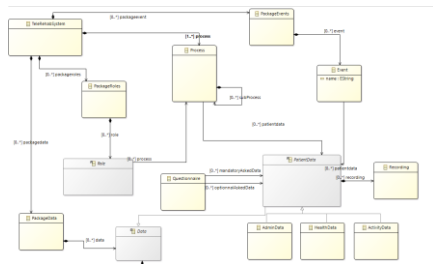


Work in progress:

► Tools to speed up TeleRehabilitation System (TRS) design

- Definition of a **modeling tool** for setting up a specific TRS focusing on a specific disease

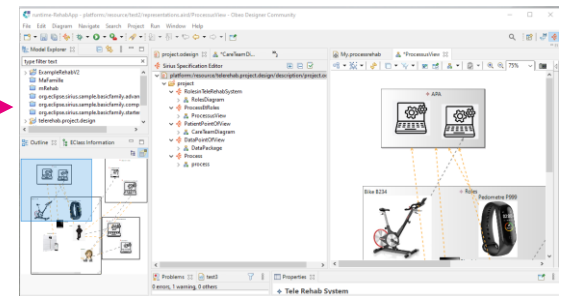
Meta-model



Description of actions on the meta-model



Graphical modeling of a specific App



Future work:

► Tools to speed up TRA development

- Definition of a **properties transformer** from natural language to UPPAAL (using boiler plates or NLP).

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REFERENCES

- A.L. Courbis, F. Arfi, T. Lambolais, F. Bughin, M. Hayot. *Semi-formal and formal specification of a telerehabilitation system for chronic respiratory diseases: methodology and feedback*, ISSRE 2023, Florence, Italy.
- F. Arfi, A.L. Courbis, T. Lambolais, F. Bughin, M. Hayot. *Formal verification of a telerehabilitation system through an abstraction and refinement approach using UPPAAL*. IET Soft. 17(4), 582–599 (2023). <https://doi.org/10.1049/sfw2.12128>, Wiley.



Projet cofinancé par le Fonds Européen de Développement Régional