# DELIVERABLE

**Project title:** LetItFlow: Active Distributed Workflow System for elderly

**Project reference number:** AAL-2013-6-128

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## D5.1 – Design field trial methodology

**Revision: 1.2**

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# ABBREVIATIONS

| | |
|---|---|
| AAL | Active and Assisted Living |
| AE | Adverse Events |
| HUVM | University Hospital Virgen Macarena |
| ISO | International Organization for Standardization |
| OSES | Short Version of the Occupational Self-Efficacy Scale |
| REO-C | Rapid evaluation and optimization cycle |
| SAE | Serious Adverse Events |
| TAM | Technology Acceptance Mode |
| UCD | User-centred design |
| UHB | University and Emergency Hospital Bucharest |
| UMUX | Usability Metric for User Experience |
| UX | User Experience |

# 1. INTRODUCTION

## 1.1 Scope and objectives of the deliverable

The main objective of this deliverable is the design of a comprehensive evaluation plan for the LetItFlow trials. The plan will propose the criteria for the assessment of the prototype and will take into account ethics, metrics, and selection of users, impact on users and the maturity of the developed technology, resource plans as well as necessary preparations at the trial sites.

The field trials evaluation methodology is based on an agile UX/UCD framework that allows for:

- Demonstrating the suitability of the produced solution for the use in a clinical setting by members of the target group (i.e., employees above the age of 50),
- Continuous end-user feedback, and
- Iterative modifications and optimizations based on the feedback received.

The trial methodology is structured in a way that it fits both trial sites in Romania and Spain with their different specializations (i.e., automated biochemistry laboratory, internal medicine and neurology ward). Moreover, the materials part of the trial methodology will be prepared in the local languages (i.e., Spanish and Romanian).

Research questions to be addressed during the Field trials:

1. How does the user perceive the LetItFlow system in terms of user-friendliness, usefulness and acceptance?
2. How does the user use the LetItFlow system? Which modules are selected by the end-users to reach the abovementioned goals? To what extent are the selected modules used?
3. Which functionalities are perceived as useful / not useful by which user and why?
4. How does the LetItFlow system influence users' working lives, if at all?
5. To what extent does LetItFlow support the environment of the user, like other health care professionals, patients, visitors, other?

## 1.2 Structure of the deliverable

The report is structured in 8 chapters:

- **Chapter 1** serves as an introduction, outlining the scope and objectives of the deliverable..
- **Chapter 2** describes the LetItFlow prototypes consisting of the different hardware options smartphone, smartwatch and desktop, along with all its functionalities that will be tested as part of the field trials. The description relates to the latest development stage, which will be used in the trials.
- **Chapter 3** gives a description of the participants to be involved in the trial, including the different roles of participants as well as inclusion and exclusion criteria.
- **Chapter 4** covers the protocol design of the field trial. It describes the Rapid Evaluation and Optimization Cycles (REO-C) methodology in detail as well as the recruitment procedure and participant involvement in the study. An English version of the informed consent form for each test site can be found at the end of the documents provided in Annex IV.
- **Chapter 5** presents the methodology of the field trials, separately for qualitative and quantitative measures. It describes the task-based thinking aloud method and the semi-structured interviews after each trial cycle. It also gives an overview of the involved questionnaires UMUX, TAM, and OSES. The

questionnaires can be found in Annex I. The corresponding practical study protocol for the task-based evaluation can be found in Annex II. The semi-structured interview guide is depicted in Annex III.

- **Chapter 6** provides information about the data analysis.
- **Chapter 7** deals with the ethical considerations with regard to the trials, covering general regulatory statements, recruitment and informed consent, security and privacy issues and data management.
- **Chapter 8** provides the bibliography of this document.

# 2. DESCRIPTION OF THE LETITFLOW SOLUTION

The LetItFlow platform offers services aimed at medical professionals (i.e., nurses, orderlies, lab technicians) above the age of 50. Different services target different members of the target population. The LetItFlow solution consists of the following components, as described in this chapter.

## 2.1 LefItFlow Hardware

### 2.1.1 Smartwatch

The Motorola Moto360 is a smartwatch that looks like a normal watch. It runs on Android wear, which enables us to reuse parts of the code used also in the smartphone solution. The LetItFlow smartwatch application allows access to the functionalities of LetApp, LetAlarm, and LetCritical. It provides the following functionalities:

- Accessing information about assigned tasks
- Receiving guidance in task execution
- Sending and receiving alerts and alarms


**Figure 1: Smartwatch Interface**

### 2.1.2 Beacon

Bluetooth beacons are devices that send a unique identifier at a fixed rate and fixed power. By receiving this signal on a Bluetooth enabled device (e.g. a mobile phone) it is possible to do get an estimate of a position. This was done by the monitor manager. The calculated locations were used by the other components for smart selection of tasks and persons. Any Bluetooth beacon that supports the iBeacon protocol can be used. We used the Kontakt,IO beacons because they were easy to configure, have a very good battery life and seemed sturdy enough for our goals.

**Figure 2: Kontakt.IO Bluetooth Beacons**

### 2.1.3 Smartphone

The smartphone running the application LetApp plays the main role for the end-users, in our case nurses and laboratory technicians. This simple application turns a client's smartphone into an intelligent mobile personal device acting as the front-end of the workflow engine. The application has been developed in Java Android and runs on the majority of Android devices (version 20 or higher).


**Figure 3: Smartphone Interface**

Basically, the application supports the employees in their daily tasks, guiding the employees throughout the business processes implemented in the workflow engine, providing the following functionalities:

- Assistance/Guidance task
- Notifications & alarms
- Internal chats
- Support in bedside care and reporting
- Training

Note that the smartphone device is complemented by the smartwatch device to avoid that employees have to carry bulky tablets or smartphones during the work day. To allow the complementary usage of both devices the interfaces are designed with the same logic and structure in mind. Similarly, relevant data is synchronized across the two devices, allowing the user to switch seamlessly from device to another.

### 2.1.4 Desktop

The desktop interface of LetItFlow is for the managers or coordinators, providing them the front-end of the workflow engine. It can be a desktop computer or laptop running any operative system. The only restrictions are that it is necessary to have internet access and a web browser because the interface is based on web technology. The aim of this tool is to provide information about the status of the LetItFlow system at all times and the capability to interact with it, such as planning the workflows, creating and assigning tasks. Aside from the above, the tool allows managing the users' profiles and credentials, launch alarms and notifications, etc.

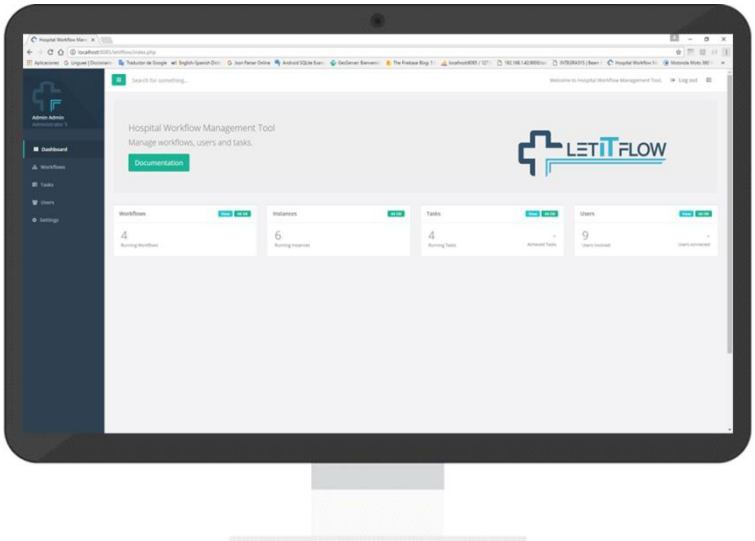



**Figure 4: Desktop Interface**

## 2.2 LetItFlow Functionalities

This section presents briefly the different use services / use cases that will be tested and validated during the field trials in the two end-user organizations (three test sites) involved in the project. This content is based on the information included in the Deliverable D2.2 where the tasks / scenarios and uses cases are defined for the *Neurology Department of the University Emergency Hospital of Bucharest* (Romania) and the *Automated Laboratory of Biochemistry General of the Hospital Universitario Virgen Macarena* (HUVM) of Seville (Spain) environments. Note that new tasks for the Internal Medicine Unit of HUVM have been included after the recommendations received during the midterm review, with the purpose to increase the marketability and to demonstrate the scalability and versatility of the LetItFlow solution such that it can be applied also to other tasks or requirements in the healthcare domain.

### 2.2.1 Login

The process by which the employee (nurse or laboratory technician) gains access to the LetItFlow system through the LetApp application. Previously, the employee had to contact the administrator (e.g. head nurse or head of laboratory) to register in the system and to get the proper credentials.

### 2.2.2 Task Menu

The task menu is the main view of LetApp and allows the employee to interact with the tasks available to the employee or his/her work role. The availability of the task to each user is intelligent and based on profile and context information (e.g. proximity or current work load). Note that the life cycle of a task, once it is instantiated in the system, proceeds along the stages “unassigned”, “assigned” and “completed”.

### 2.2.3 Task Status

The ideal process that the employee should follow when performing a task, is first to take the task from the list (changing task status to “assigned”) and later confirm it once it is finished (changing task status to “completed”). To avoid unnecessary micro-management of the tasks and annoying employees by lengthy descriptions and excessive process steps in the application, some tasks modify their status or disappear automatically from the task list due to the feedback from external systems (e.g. HIS, laboratory software, inventory management software, shift-change management software, etc.).

### 2.2.4 Task Content/ Training

The employee has the possibility to access related content to the tasks and sub-tasks before performing the task itself. This functionality provides information about how to proceed with the task. The associated content could be video, audio, text or links to external applications.

### 2.2.5 Sending Alarm

The employee can send alarms or notifications through the LetApp application using the smartwatch or smartphone, requesting the help from other employees or warning them about any problem. The alarm can be sent to a specific employee or role or is based on the location or context. The employee can attach information to the alarm like image or audio. In the case of the smartwatch, the alarm is sent to other employees based on their location and text mode only.

### 2.2.6 Receiving Alarm/Notification

The employee can receive notifications or alarms in the smartphone or smartwatch through the LetApp application. If the application is running in the background, the employee receives a notification in the Android status bar of the device, together with a sound and vibration to catch the employee's attention.

### 2.2.7 Sending Message

The employee sends text messages to other employee to communicate some specific issue. These messages could attach image and audio content.

### 2.2.8 Receiving Message

The employee can receive text messages sent from other employees about some specific issue. These messages could include image and audio content.

### 2.2.9 Mentoring

The employee can request other colleagues to collaborate with them for performing a specific task. The employee list provided by LetApp is based on the task history (employees that performed it previously) and their profiles.

### 2.2.10 Workflow Management

The manager (e.g. head nurse or laboratory technician) can constantly check the status of the workflow instances for the current shift. This allows managing in real time which tasks are running and who is performing which one.

### 2.2.11 Insert New Tasks

A scheduling tool is provided to the manager of the ward/laboratory that allows selecting the daily workflows (modelled of the procedures performed by the employees) and their status and errors. The manager can also create and send new tasks to a specific or role.

### 2.2.12 Bedside Reporting

The employee can note particular data of the patient via the LetApp application (e.g. temperature, high pressure, heart rate, etc.). By having the possibility to document those data instantly while in the patient's room, the employee does not have to recollect the data afterwards. Thus, this ensures that employees do not forget to document important patient information.

### 2.2.13 Shift Change

At the beginning of the shift, the employee receives a summary with all relevant information from the previous shift via the LetApp application. This helps to avoid miscommunications and misunderstandings and allows reducing the required time currently needed to pass the information to the next shift.

### 2.2.14 Logoff

Process by which the user disconnects or leaves the LetApp application.

# 3. PARTICIPANTS' DESCRIPTION

## 3.1 Participants and Roles

### 3.1.1 Instructors

Instructors are either head nurses or head laboratory assistants. Head nurses have the role as instructors, as being responsible for creating instructions / features specific to monitoring and guiding employees (nurses) in their daily activities. Similarly, head laboratory assistants supervise their team and assign tasks to them.

### 3.1.2 Instruction receivers

Instructions receivers are older employees – nurses, orderlies or laboratory assistants – belonging to the project target group / study group, those who will benefit from the tools / devices and computing infrastructure performance of the project. In the project this category of users is represented by nurses and orderlies in the two hospitals involved in the project: University Emergency Hospital Bucharest, Romania and University Hospital Virgen Macarena Seville, Spain.

## 3.2 Criteria for inclusion and exclusion

The following **inclusion criteria** will be applied for the recruitment of participants.
Persons can take part in the study if:

- They are working in one of the trial sites either as head nurse, nurse or head laboratory, assistant nurses, orderlies, technicians.

The following **exclusion criteria** will be applied for the recruitment of participants.
Persons cannot take part in the study if:

- They are not fluent in the respective language of the test site (Spanish or Romanian).
- They have serious visual and cognitive impairments that impact the use of the LetItFlow system.
- They refuse to sign the informed consent.

Additionally, the majority of participants should be above the age of 50 years. However, one or two younger participants per site are okay to evaluate their opinions as well. A good balance between tech-savvy and non tech-savvy test users is further preferred.

# 4. PROTOCOL DESIGN

The field trial evaluation methodology relies on agile *UX/UCD* framework consisting of four reoccurring parts (cycles) lasting three weeks each (see section 4.1 for a detailed description). Starting from M32, 4 prototypes for each recruiting centre will be available for use. Therefore each clinical centre will be able to enrol at least 4 participants per cycle. Having four cycles with each eight participants (4 in Romania and 4 in Spain), we will altogether have 32 contacts to end-users, 16 in Spain and 16 in Romania. Due to the irregular shifts of nurses, it cannot be guaranteed that one test user can use the LetApp for two or even three consecutive days during the trial phase (Day 1 to Day 3; see Table 1). At each of the three defined test sites eligible subjects will be invited to take part in the field trials. Members of the LetItFlow consortium involved in the field trials will prepare the LetItFlow prototype(s) at each test site and will instruct participants on the use of the prototypes, the objectives of the field trials and their participation.

## 4.1 Rapid evaluation and optimization cycles (REO-C)

The field trials evaluation framework described in this section integrates an agile development process with user experience (UX) and user-centered design (UCD) methods. In recent years, such hybrid approaches have become increasingly popular with academics as well as practitioners as they manage to combine the

strengths of both approaches: a focus on functionality and quick delivery as well as a focus on user satisfaction and usability (Hussain, Slany, & Holzinger, 2009; Jurca, Hellmann, & Maurer, 2014; Russ et al., 2010; Schwartz, 2013).

In devising the LetItFlow Agile UCD / UX framework, we defined two main goals. The framework must allow for (1) continuous end-user feedback based on user-centered design (UCD) principles and (2) continuous modifications and optimizations. In order to achieve these goals, close collaboration between the technical and user-experience (UX) teams is essential.

Figure 54 provides an overview of the evaluation framework, its procedure and timing. The study period is subdivided in four reoccurring parts (cycles) lasting three weeks each. The trial in the hospital context will start in the beginning of September 2017 using the then current version of the software. After the first round of evaluations (week 1), technical partners optimize the prototypes based on the feedback from users. In this period, the project will try to address as much of the feedback as possible, trying of course to maintain a high level of quality of the overall solution, without jeopardizing the integrity of the next round of evaluations. After this first cycle, the project will execute three subsequent cycles alternating between evaluation and optimization.

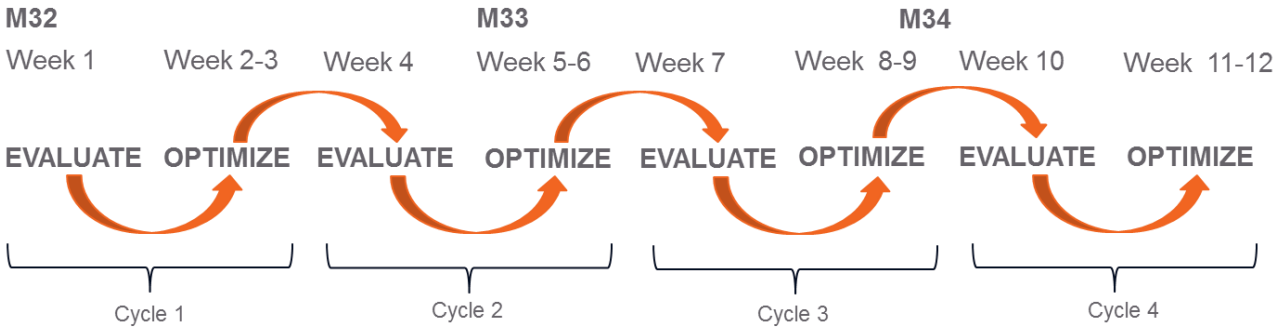



**Figure 5: The LetItFlow Agile UCD / UX framework: Rapid evaluations and optimization cycles (REO-C)**

**The following section describes the procedure of each cycle in detail (see also Table 1):**

| | |
|---|---|
| **Pre-Evaluation** | D-X is the day of the inclusion of the participant in the study. Participants will be briefed about the purpose of the study and all the technical aspects concerning the LetItFlow services. After this, the informed consent and the privacy policy will be explained and handed out to them. After the informed consent is signed, baseline data of participants will be gathered. |
| **Day 1** | With D1, the actual evaluation starts. As the participants already know the aim of the study, the evaluator will just briefly discuss the plan of this day's intervention (see also chapter 5.1.1 for what this explanation should cover). For this, the evaluator will rely on a so-called "thinking aloud" approach (Boren & Ramey, 2000). To get valid information from participants, the evaluator will explain this methodology to the participant and give an example of how it works, as described in chapter 5.1.1.<br><br>**Part 1:** The smartphone and the smartwatch with the installed LetItFlow solution are handed out to the participants, who are asked to try out the application on their own without receiving any explanations by the evaluator. When giving the devices to the participants, the displays already show the login screen of the LetItFlow application(s). During this first task, the evaluator reminds the participant to think aloud and takes notes of the participant's comments.<br><br>**Part 2:** Following the first hands-on experiences of the participant with the LetItFlow solution, task-based evaluations will allow to gather more detailed information of the LetItFLow usage in different work situations. The evaluator describes the first task to the participant and then asks the participant how s/he would proceed in the situation by using the LetItFlow application. Following that, the evaluator will ask some questions |

| | |
|---|---|
| | regarding usability. The detailed task description to be performed by the participant including the questions asked by the researcher can be found in **Annex II**.<br><br>After the task-based evaluations, the evaluator then encourages the participant to use the LetItFlow solution in his/her real work context as much as possible until Thursday (D4) of the same week. Further, the evaluator and the participant already schedule an appointment for the short interview on D4. |
| **Day 2 and 3** | This is the intervention period. During these two days participants will use the services implemented in LetItFlow. During this phase, the participants will not have contact with project members. However, in case they experience problems with the system or the study in general, participants are able to contact the evaluator whenever needed. |
| **Day 4** | **Part 1**: On D4, the evaluator will conduct a short interview with the participant. Depending on the coordination of participants' schedules, those interviews can be conducted either individually or together with other participants in a group setting. The interview is based on a semi-structured interview guide (see Annex III). This means, the evaluator does not have to strictly stick to the questions and their order but should try to get participants' views on all involved aspects of the interview guide. The interviews are voice-recorded to allow the evaluator to play back participants' comments at a later stage. Additionally, the evaluator will take notes from the participants' comments in an evaluation spreadsheet.<br><br>**Part 2**: After the interviews, participants are asked to fill in quantitative questionnaires regarding usability and technology acceptance. |
| **Day 5 and 8** | To allow for a smooth communication of participants' feedback from the evaluators to technical partners, the evaluators rephrase the feedback in specific recommendations for optimization. A common spreadsheet is set up to gather all recommendations in one common document (see Annex V). This document also includes columns for evaluators to rate the importance of each recommendation. The evaluators' ratings should be based on their perceived urgency of problems experienced by the participants during D1 to D3. |
| **Day 9** | A Skype appointment will be scheduled for both the evaluators and the technical partners to go through and discuss the recommendations. The recommendation document serves as basis for discussions. The main focus of this discussion is to find consensus on how the recommendations coming from participants can be realized from a technical perspective. All partners will decide on a priority rating of all optimizations based on the evaluators' ratings regarding the importance per recommendation and the technical partners' estimation of how long the specific optimization will take. |
| **Day 10 to 21** | The following eight working days are dedicated to the optimization of the LetItFlow application. On D21, the iterated version is ready to be tested in the second cycle of evaluations. |

**Table 1: One full cycle of evaluations and optimizations: timeline and activities**

| Day | | Task(s) | Required Partner |
|---|---|---|---|
| D-X | | Project explanation; Participants sign informed consent | Trial Partner |
| D1 | MO | Task-based thinking aloud (1h)<br>Use in working context (trial partner only required in case of problems) | Trial Partner |
| D2 | TU | Use in working context | (Trial Partner) |
| D3 | WE | Use in working context | (Trial Partner) |
| D4 | TH | Short interview about experiences in last days (individual or group setting)<br>Quantitative Measures (print-outs) | Trial Partner |

| | | | |
|---|---|---|---|
| D5 | FR | Analysis: rephrasing interview feedback in recommendations (in shared excel sheet) and rating the recommendations | Trial Partner |
| D6 | SA | Weekend | |
| D7 | SU | Weekend | |
| D8 | MO | Analysis: rephrasing interview feedback in recommendations (in shared excel sheet) and rating the recommendations | Trial Partner |
| D9 | TU | Skype to discuss recommendations (2 h) | Trial Partner; Tech. Partner |
| D10 | WE | Optimization of LetItFlow solution | Tech. Partner |
| D11 | TH | Optimization of LetItFlow solution | Tech. Partner |
| D12 | FR | Optimization of LetItFlow solution | Tech. Partner |
| D13 | SA | Weekend | |
| D14 | SU | Weekend | |
| D15 | MO | Optimization of LetItFlow solution | Tech. Partner |
| D16 | TU | Optimization of LetItFlow solution | Tech. Partner |
| D17 | WE | Optimization of LetItFlow solution | Tech. Partner |
| D18 | TH | Optimization of LetItFlow solution | Tech. Partner |
| D19 | FR | Optimization of LetItFlow solution;<br>Technical pre-testing to assure that the next iteration is ready to be evaluated | Tech. Partner |
| D20 | SA | Weekend | |
| D21 | SU | Weekend | |

**Table 2: Trial planning**

## 4.2 Recruitment and Consent

The recruitment of participants is performed by the LetItFlow end-user partners at the University Hospital Virgen Macarena (HUVM) and the University and Emergency Hospital Bucharest (UHB).

The two end-user partners HUVM and UHB conduct the evaluations in the field and serve as the main contacts for the participants. For this representatives of HUVM and UHB will follow the procedure described in Table 1. The informed consent of participants is obtained at the very beginning, prior to the start of the first evaluation and optimization cycle.

## 4.3 Participants' rights

The participation in this study is voluntary. Employees from the two end-user organizations, HUVM and UHB, can choose to refuse to participate or can withdraw from the study at any time. In such case, there are no consequences for the involved party whatsoever. We may ask participants withdrawing from the study to provide a short explanation regarding their choice. The data gathered until that moment will be kept and used in the analyses, unless participants explicitly wish to have their data removed (opt-out). Participants will be informed about their rights prior to the start of the first evaluation cycle, after which they are requested to sign an informed consent (see Annex IV).

## 4.4 Dealing with attrition

Strategies to manage attrition during the field trial period are fundamental. Participants may drop out of the study for various reasons (e.g., unwillingness to continue/second thoughts, sickness and other unexpected events). Based on experience an attrition rate of 10-20% is realistic. In such a case, all existing participant data will be used for analysis, unless participants explicitly wish to have their data removed. Furthermore, participants dropping out of the study will be replaced immediately, when feasible.

# 5. MEASURES AND OPERATIONALIZATION

## 5.1 Qualitative Measures

### 5.1.1 Task-based thinking aloud

The participants will be asked to perform specific tasks (see Annex II) with the support of certain LetItFlow modules. During the execution of these tasks, the participants will be asked to think aloud to capture as much valuable information as possible. Thinking aloud is a broadly used technique in usability testing that should follow some standards as described by Boren and Ramey (2000):

**1) Collect and Analyze Only "Hard" Verbal Data**

Data gathered with the thinking aloud technique can be categorized in three levels (Boren & Ramey, 2000; Ericsson & Simon, 1980).

- Level 1 Verbalizations are those that need not be transformed before being verbalized during task performance (e.g. verbalizing sequences of numbers while solving a math problem because numbers can be verbalized in the same form as they were originally encoded in short-term memory).
- Level 2 Verbalizations are those that must be transformed before being verbalized during task performance (e.g. images or abstract concepts).
- Level 3 Verbalizations are those that require additional cognitive processing beyond that required for task performance or verbalization (e.g. filtering processes like "verbalize only information related to topic X").

It is recommended just to use Level 1 and 2 data. Level 3 data should not be used for analysis, thus, the researcher should not request inferences about the subjects' own cognition, and information retrieved from long-term memory. Also, any outside influence, including any comment or prompt from the researcher, turns subsequent verbalizations into Level 3 data because the normal flow of information in short-term memory during the task has been altered.

**2) Practice thinking aloud with the participant**

Before starting with the first evaluation, the evaluator will explain the participant the method of Thinking Aloud and gives a brief example:

> *"Before we start with the evaluation, I would like to explain to you what we are going to do within the next hour. First, I am going to show you the LetItFlow prototypes and you can get a first impression about the features by trying out the application. Then we will, together, go through eight usage tasks / scenarios of the LetItFlow application. During all those tasks, I would like to ask you to think aloud. Thinking aloud means that you try to speak aloud everything that comes to your mind when trying out the system. Try to speak constantly "as if alone in the room" without regard for coherency. I will remind you to think aloud. It is not necessary to verbalize in full or correct sentences. This method allows me to get a detailed impression of your experience when using the application. Importantly, the aim is not to evaluate you but solely the LetItFlow system. This helps us to improve the system and to make sure that it really fits the needs of people who are going to use it in the future. After each task, I will ask you some questions related to the task. If you have any questions, now or during the evaluation, please don't hesitate to ask me any time."*

**Example for Thinking Aloud**

The evaluator should then give a short example of how the Thinking Aloud method works by pouring some water from a carafe into a glass.

E.g. "*I take the carafe with my right hand at its handle. With the left hand I grab the glass and raise it to the carafe's spouse. Then I carefully tilt the carafe until the water flows into the glass …*"

**3) Remind the participant to think aloud**

Reminders should come after a predetermined period of silence (perhaps 15–60 seconds) and should be as short and nondirective as possible. Reminders should also not encourage a sense of personal contact or heighten awareness of the researcher's presence (Boren & Ramey, 2000). "Keep talking" is Ericsson and Simon's recommended reminder. After a task begins, the only interaction should be the reminder to think aloud, as needed.

### 5.1.2 Semi-structured interviews

After the LetItFlow solution has been used in the work context for three days, both researcher and participant will meet again for a semi-structured interview to evaluate their experiences with the LetItFlow prototype over the last days. The semi-structured interview is a rather free conversation with the participant(s), in which there is a predetermined list of questions that are covered in the same order for each participant (Miles & Gilbert, 2005).

The semi-structured interview guide with the list of questions can be found in Annex III.

## 5.2 Quantitative Measures

At the end of each cycle, the researchers will hand out questionnaires to participants assessing the usability of the LetItFlow application (The Usability Metric for User Experience), as well as the technology acceptance (Technology Acceptance Model) and occupational self-efficacy (Short Version of the Occupational Self-Efficacy Scale).

### 5.2.1 The Usability Metric for User Experience (UMUX)

The Usability Metric for User Experience (UMUX) is a four-item Likert scale used for the subjective assessment of an application's perceived usability. It is designed to provide results similar to those obtained with the 10-item System Usability Scale, and is organized around the ISO 9241-11 definition of usability (Finstad et al., 2010). These are the questions included in the UMUX questionnaire (an adaptation to the LetItFlow study can be found in ANNEX I):

1. *[This system's] capabilities meet my requirements.*

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| *Strongly Disagree* | | | | | | *Strongly Agree* |

2. *Using [this system] is a frustrating experience.*

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| *Strongly Disagree* | | | | | | *Strongly Agree* |

3. *[This system] is easy to use.*

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| *Strongly Disagree* | | | | | | *Strongly Agree* |

4. *I have to spend too much time correcting things with [this system].*

| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
|---|---|---|---|---|---|---|
| *Strongly Disagree* | | | | | | *Strongly Agree* |

**Figure 6: Usability Metric for User Experience questionnaire**

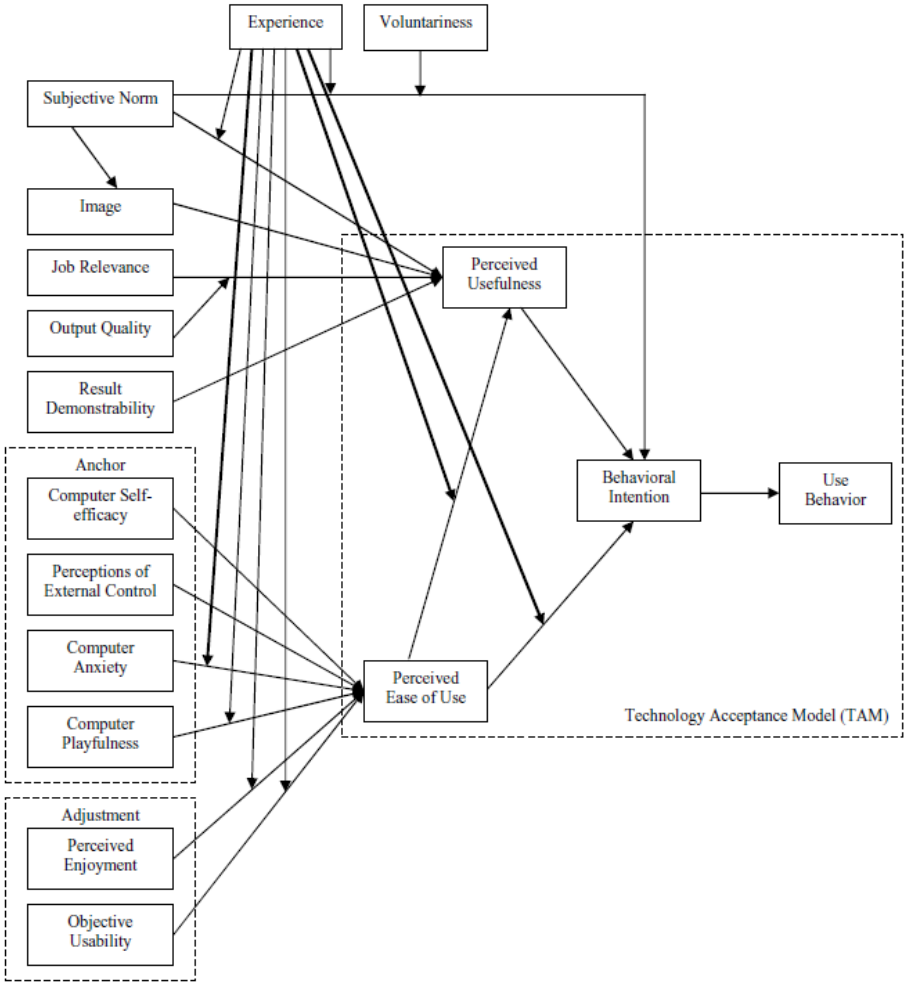
### 5.2.2 Technology Acceptance Model (TAM)

The TAM was developed to predict individual adoption and use of new information technologies. The fundamental variables of this model are **perceived usefulness** (PU) and **perceived ease of use** (PEOU). PU is defined as "the degree to which a person believes that using a particular system would enhance his or her job performance" and PEOU is defined as "the degree to which a person believes that using a particular system would be free of effort." (F. Davis 1989a).

Davis´ main theoretical foundation for the TAM is the model of Fishbein (1967) – the Theory of Reasoned Action, which was further elaborated into the Theory of Planned Behavior (Ajzen 1991), in which an actual **behavior** has a linear relationship to the **behavioral intention** (BI) regarding this actual behavior. BI is a function of the attitude towards the behavior and the **subjective norm** regarding this behavior.

After focusing almost completely on PEOU and PU in the original TAM (Davis, 1985; Davis, 1993; Davis, 1989a, Davis, 1989b), in later research the focus is on **antecedents of PEOU** (see left part of Figure 7) (Venkatesh & Davis 1996).

The full TAM questionnaire can be found in Annex I.




[a]Thick lines indicate new relationships proposed in TAM3.

**Figure 7: Technology Acceptance Model 3 (Venkatesh & Bala, 2008)**

### 5.2.3 Short Version of the Occupational Self-Efficacy Scale (OSES)

Self-efficacy is defined as the confidence an individual has in her or his ability to cope with difficult tasks or problems or in other words the belief in one's ability to successfully fulfill a task (Rigotti, Schyns, & Mohr, 2008). In organizational research, self-efficacy has been shown to directly relate to job satisfaction (Judge & Bono, 2001) and performance (cf. Judge & Bono, 2001; Stajkovic & Luthans, 1998). The Short Version of the Occupational Self-Efficacy Scale refers to the competence that a person feels concerning the ability to successfully fulfill the tasks involved in his or her job. Schyns and von Collani introduced the short form of the Occupational Self-Efficacy Scale, which is comprised of eight items and shows equally good measurement characteristics as the original long version. Rigotti et al. (2008) even used a shorter version, based on statistical item characteristics, with only six items. This version will be used in the LetItFlow trials and can be found in Annex I. The items are rated on a 6-point rating scale ranging from 1 (not at all true) to 6 (completely true). High values reflect high occupational self-efficacy.

### 5.2.4 Use of the System

With the intention to maximize and provide the best possible user experience, verify the functionality and to improve the developed applications, LetItFlow server provides a REST service to gather data about any relevant event and/or occurrence which could happen during the trials to be analysed a posteriori, providing detailed information about the user experience and the usage (it will be used as complement to the feedback provided by the users after each test cycle).

The information reported include from, for example, login/logout on the system or application, capture task transactions (executed, pending, duration, assigned user, etc.), gesture tracking, information about received/sent alarm/notification, use duration, errors or crashes during the use of application, etc.

The structure of the reported information from the platforms into the database is as follows: Timestamp (Date & Time) + Type (Error, Debug, Warning, Info…) + Platform (Server, Smartphone or Smartwatch) + User (Username) + Description.

# 6. DATA ANALYSIS

## 6.1 Qualitative data

The task-based evaluations and the interviews and will be analysed by the partners in Romania and Spain. To allow a fast optimization of the prototype, the feedback of participants will be rephrased in recommendations for changes to be passed to the technical partners. Therefore, researchers in Romania and Spain will identify those recommendations, write them in a common spreadsheet (see Figure 8) and rate their severity. The following questions affect the severity ranking:

- **The frequency of the problem:** Frequently? Rarely?
- **The impact of the problem:** How well can the user handle the problem?
- **The persistence of the problem:** Can users skip the problem when it occurs or do they need to resolve the problem every time?

Based on those questions, the evaluation partners (UHB, HUVM) will rate the severity with a score from 1 to 4, which means:

- 1 = Severe problem
  The problem is likely to result in an abortion of the interaction - a correction is absolutely necessary.
- 2 = Relevant problem
  The problem makes the task very difficult for the user; the user is likely to abort the interaction - a correction is highly recommended.
- 3 = Minor problem
  Users perceive the task as unpleasant and annoying. The task will probably continue, but it can lead to an image or fun loss.
- 4 = Nice to Have
  A change would be desirable and would give the user a more comfortable feeling in solving his tasks.

| Tasks / User Interface | Evaluation partner | Observation (please describe the issue that came up during the evaluations) | Recommendation for change (please indicate how the observed issue can be solved) | Rating HUCM | Rating UHB | Mean rating | recomm. adapted | Comments from technica |
|---|---|---|---|---|---|---|---|---|
| | | | Rating options: 1=Severe problem (Th 2=Relevant problem (T 3=Minor problem (Use 4=Nice to Have (A cha | | | | | |
| Task 1: Login/logout and Task menu | | | | | | | | |
| | e.g. Partner UHB | e.g. participant cannot read text | e.g. enlarge the font and improve the contrast by using a lighter blue background | 2 | 1 | 1.5 | yes | |
| Task 2: Task Content / Training | | | | | | | | |
| Task 3: Sending alarms | | | | | | | | |

Participants list | Cycle1: Task-based evaluation recommendations | Cycle1: Interview recommendations | Cycle 1: Questionnaires | Explore

**Figure 8: Recommendation spreadsheet**

This recommendation spreadsheet is going to be used in the telephone conference together with the technical partners to present and discuss the recommendations and how the LetItFlow prototypes can be optimized accordingly. The average severity rating will help to choose which issues to tackle first.

## 6.2 Quantitative data

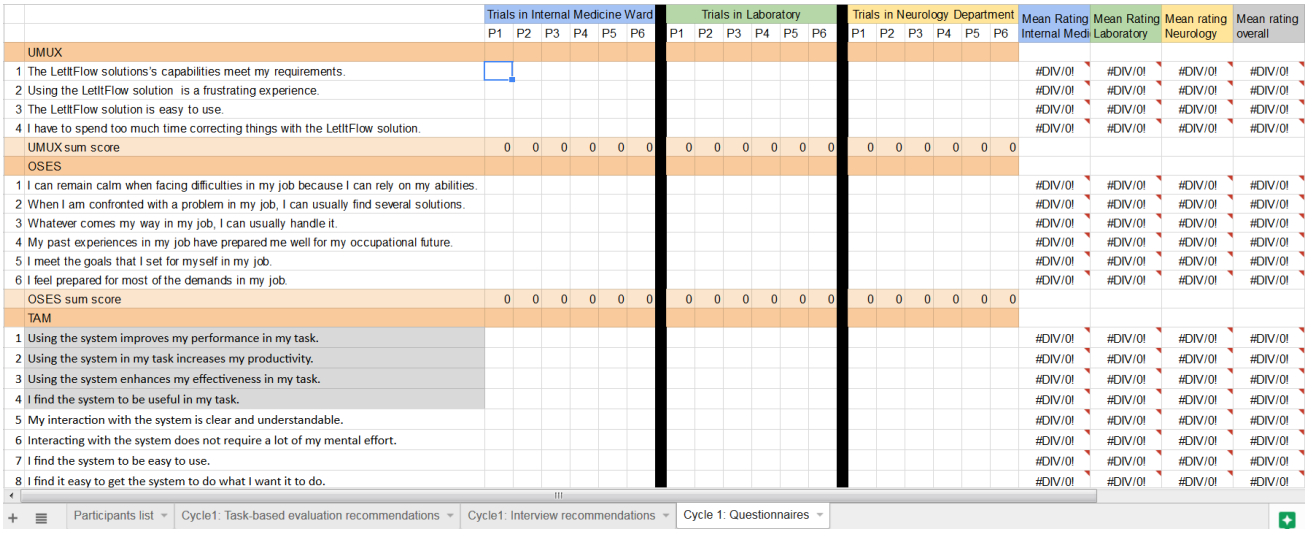
The questionnaires and the usage logging will be statistically analysed with a focus on differences in the job role, gender, age, and residence. The usage logging date will be processed and analysed by Integrasys. Quantitative analysis of the questionnaires will be performed centralized by AIT at the end of the field trials.

The evaluation partners are asked to fill the answers to questionnaires as well as sociodemographic data in the common evaluation spreadsheet (see Figure 9 and Figure 10) in order to have all data available in one document ready to be analysed.

| Internal Medicine Department | | | | | | | Laboraoratory | | | | | | | Neurology Department | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Cycle 1 | | | | | | | Cycle 1 | | | | | | | Cycle 1 | | | | | | |
| Person acronym | Initials (First na | Year of birth | Gender | Job role | Job experience in years | Working hours per week | Person acronym | Initials (First na | Year of birth | Gender | Job role | Job experience in years | Working hours per week | Person acronym | Initials (First na | Year of birth | Gender | Job role | Job experience in years | Working hours per week |
| P1 | | | | | | | P1 | | | | | | | P1 | | | | | | |
| P2 | | | | | | | P2 | | | | | | | P2 | | | | | | |
| P3 | | | | | | | P3 | | | | | | | P3 | | | | | | |
| P4 | | | | | | | P4 | | | | | | | P4 | | | | | | |
| P5 | | | | | | | P5 | | | | | | | P5 | | | | | | |
| P6 | | | | | | | P6 | | | | | | | P6 | | | | | | |
| Cycle 2 | | | | | | | Cycle 2 | | | | | | | Cycle 2 | | | | | | |
| Person acronym | Initials (First na | Year of birth | Gender | Job role | Job experience in years | Working hours per week | Person acronym | Initials (First na | Year of birth | Gender | Job role | Job experience in years | Working hours per week | Person acronym | Initials (First na | Year of birth | Gender | Job role | Job experience in years | Working hours per week |
| P1 | | | | | | | P1 | | | | | | | P1 | | | | | | |
| P2 | | | | | | | P2 | | | | | | | P2 | | | | | | |
| P3 | | | | | | | P3 | | | | | | | P3 | | | | | | |
| P4 | | | | | | | P4 | | | | | | | P4 | | | | | | |
| P5 | | | | | | | P5 | | | | | | | P5 | | | | | | |
| P6 | | | | | | | P6 | | | | | | | P6 | | | | | | |
| Cycle 3 | | | | | | | Cycle 3 | | | | | | | Cycle 3 | | | | | | |
| Person acronym | Initials (First na | Year of birth | Gender | Job role | Job experience in years | Working hours per week | Person acronym | Initials (First na | Year of birth | Gender | Job role | Job experience in years | Working hours per week | Person acronym | Initials (First na | Year of birth | Gender | Job role | Job experience in years | Working hours per week |
| P1 | | | | | | | P1 | | | | | | | P1 | | | | | | |
| P2 | | | | | | | P2 | | | | | | | P2 | | | | | | |
| P3 | | | | | | | P3 | | | | | | | P3 | | | | | | |
| P4 | | | | | | | P4 | | | | | | | P4 | | | | | | |

Participants list | Cycle1: Task-based evaluation recommendations | Cycle1: Interview recommendations | Cycle 1: Questionnaires | Explore

**Figure 9: Sociodemographic data spreadsheet**



| | | Trials in Internal Medicine Ward | | | | | | Trials in Laboratory | | | | | | Trials in Neurology Department | | | | | | Mean Rating Internal Medi | Mean Rating Laboratory | Mean rating Neurology | Mean rating overall |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | P1 | P2 | P3 | P4 | P5 | P6 | P1 | P2 | P3 | P4 | P5 | P6 | P1 | P2 | P3 | P4 | P5 | P6 | | | | |
| | UMUX | | | | | | | | | | | | | | | | | | | | | | |
| 1 | The LetItFlow solutions's capabilities meet my requirements. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| 2 | Using the LetItFlow solution is a frustrating experience. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| 3 | The LetItFlow solution is easy to use. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| 4 | I have to spend too much time correcting things with the LetItFlow solution. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| | UMUX sum score | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | OSES | | | | | | | | | | | | | | | | | | | | | | |
| 1 | I can remain calm when facing difficulties in my job because I can rely on my abilities. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| 2 | When I am confronted with a problem in my job, I can usually find several solutions. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| 3 | Whatever comes my way in my job, I can usually handle it. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| 4 | My past experiences in my job have prepared me well for my occupational future. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| 5 | I meet the goals that I set for myself in my job. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| 6 | I feel prepared for most of the demands in my job. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| | OSES sum score | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | | | |
| | TAM | | | | | | | | | | | | | | | | | | | | | | |
| 1 | Using the system improves my performance in my task. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| 2 | Using the system in my task increases my productivity. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| 3 | Using the system enhances my effectiveness in my task. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| 4 | I find the system to be useful in my task. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| 5 | My interaction with the system is clear and understandable. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| 6 | Interacting with the system does not require a lot of my mental effort. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| 7 | I find the system to be easy to use. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |
| 8 | I find it easy to get the system to do what I want it to do. | | | | | | | | | | | | | | | | | | | #DIV/0! | #DIV/0! | #DIV/0! | #DIV/0! |

Participants list | Cycle1: Task-based evaluation recommendations | Cycle1: Interview recommendations | Cycle 1: Questionnaires

**Figure 10: Questionnaire scores spreadsheet**

# 7. ETHICAL CONSIDERATIONS

## 7.1 Regulation statement

This study will be conducted according to the principles of the Declaration of Helsinki (64th WMA General Assembly, Fortaleza, Brazil, October 2013) and in accordance with The Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 (amended with the regulation (EC) No 1882/2003) on the protection of individuals with regard to the processing of personal data and on the free movement of such data. During and after the execution of LetItFlow, the consortium will pursue a policy of strict adherence to the national and international directives, guidelines, and regulatory procedures. Safety and Security will be dealt with by applying the relevant standards and directives ("MDD", FDA, CE, EMC, ISO 9000, detailed risk analysis, ISO and CEN).

## 7.2 Recruitment and Consent

Article 17 of the Protocol to the Convention on Human Rights in Biomedicine or Biomedical Research states: "*No research on a person may be carried out without the informed, free, express, specific and documented consent of the person*".

This places a legal obligation on researchers to obtain and record consent from participants or their guardians, on the basis of information that should be given to them before their participation begins. In the present project, all participants will be asked in advance to state by signing an informed consent form that they are fully aware of the experimental procedure, the potential risks or benefits (if any) and that their participation is completely voluntary. Participants must be given the right to withdraw from any given research, at any time without penalty and without providing reason. Participants can also require that their data be withdrawn from the study and destroyed. Participants will be provided with information sheets, consent forms and data use agreements. There will be arrangements for safe and straightforward cessation of use by an individual who initially agreed to participate but later decides to withdraw from the study.

Informed consent forms will include all or (as appropriate) subsets of the following details:

- that the project involves research,
- overall purpose of the project,
- the number of subjects involved in the project,
- experimental procedure,
- potential risks and benefits,
- the alternative procedures of treatment that may be available to subjects and their potential benefits and risks,
- inclusion/exclusion criteria,
- end points,
- the person to contact for further information regarding the project
- the rights of project subjects,
- whom to contact in the event of project related injury,
- reimbursements to participants (in line with common practice),
- planned use of the data,
- possible commercial exploitation.

## 7.3 Security and privacy issues

### 7.3.1 Events

In accordance to national guidelines (i.e. Spanish Law 14/2007, July 3rd, about biomedics research; Romanian Law nr. 206/27.05.2004, about ethics in scientific research, technological development and innovation, Romanian Law nr. 677/2001, about personal data privacy), the investigator will inform the subjects and the reviewing accredited EC if anything occurs, on the basis of which it appears that the disadvantages of participation may be significantly greater than was foreseen in the research proposal. The study will be suspended pending further review by the accredited EC, except insofar as suspension would jeopardize the subjects' health. The investigator will take care that all subjects are kept informed.

### 7.3.2 Adverse Events and Serious Adverse Events

Adverse events (AEs) are defined as any undesirable experience occurring to a subject during the study, whether or not considered related to the experimental intervention. All adverse events reported spontaneously by the subject or observed by the investigator or his staff will be recorded.

A serious adverse event (SAE) is any untoward medical occurrence or effect that at any dose:

- results in death;
- is life threatening (at the time of the event);
- requires hospitalization or prolongation of existing patients' hospitalisation;
- results in persistent or significant disability or incapacity;
- is a congenital anomaly or birth defect;
- any other important medical event that may not result in death, be life threatening, or require hospitalization, may be considered a serious adverse experience when, based upon appropriate medical judgement, the event may jeopardize the subject or may require an intervention to prevent one of the outcomes listed above.

The sponsor will report the SAEs to the accredited EC that approved the protocol. Considering the length of the study and population (older adults) various SAEs are expected. However, an association between the SEAs and study or intervention is unlikely. For this reason every 6 months a line listing of the SAEs will be provided.

### 7.3.3 Follow-up of adverse events

All AEs will be followed until they have abated, or until a stable situation has been reached. Depending on the event, follow up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist.

### 7.3.4 Handling and storage of data and documents

Data is handled confidentially and encoded, in compliance with the National laws on Protection of Personal Data. The data are filled in on separate forms, where only a personal, not reducible number assigned to the particular subject appears; not a name. The data from the questionnaires will also be related to the unique number that is attached to the older adult. This data are stored safely, and only researchers involved in the project will have access to this data. Besides, data are stored digitally using numerical coding for 15 years. The key to the code is only accessible by the investigator. When necessary, data can be traced to an individual subject using a subject identification code list, which is safeguarded by the investigator. At the end of the intervention period, only researchers involved in this project will have access to the data.
The data from all subjects will only be used for statistical and scientific purposes and the subjects give their permission to do so, according to the informed consent. All data used n publications will be anonymized..

The LetItFlow application will not use any data regarding the patients admitted in the hospital - their name, ID or medical conditions – it is used only the number of the bed and of the room where the patient is located and only part of the medication used but there will be no association between the name of the patient and tasks to be done. So there will be no problems regarding privacy of the medical act because this means information regarding the patient, information that are not necessary for a good functioning of the LetItFlow system.

## 7.4 Use of the LetItFlow system in the hospital context

### 7.4.1 Wearing smartwatches in the hospital context

There are no EU directives and regulation regarding the usage of a smartwatch in different hospital environments. In different countries there are different directives for nurses and orderlies which regulate their profession but not this issue regarding wearing a smartwatch.
In countries where this issue is not well established the decision can be made by the manager of the hospital. On the other hand, smartwatches may be used in emergency hospitals and also in hospitals with chronic patients where the personnel are allowed to wear classic watches or bracelets. We should mention that in the

daily practice of a nurse, she/he measures the vital signs (heart rate and number of respiratory movements per minute) using a regular watch. This is the reason why in Romania and some other European countries there are no general restrictions regarding the wearing of a normal watch/smartwatch. For instance, in Romania there are some national regulation policies like the Order 1101/2016 regarding the approval of the regulatory documents for preventing the health-care associated infections in which there are no specifications considering the interdiction to wear a smartwatch. In the internal regulation of the hospital UHB it is mentioned that the medical personnel should at least remove the rings when washing /cleaning hands. In some EU countries there are specific pocket-watches used by nurses and this type of watch eliminates the issue of health-care associated infections but in this case the smartwatch cannot measure the vital signs and the alarm will not be triggered automatically but only by touching the screen.

### 7.4.2 Entering sensitive data in the LetApp

Regarding the privacy issues related to nurses there is no problem if the information are stored on a computer inside the hospital because the hospital already has all these information. On the server will be stored only the username and password. The manager of the hospital may decide if there is a need for a confidentiality agreement between the hospital and the institution which own/developed the LetItFlow system and the server. Also the institution that implements the system may register as a personal data operator at the National Authority for Personal Data Processing. Also, there will be no ethical and legal issues during the field trials as every nurse that participates to the trials signed an informed consent before inclusion in the project.

### 7.4.3 Training materials provided by the LetAPP

Regarding the training material provided to the nurses via the LetItFlow system, the application will be customized according to the specific needs of each department of the hospital and the information regarding different specific procedures will be displayed according to the internal protocols and guidelines. There are no problems if the training contains only information regarding activities of the organization of the specific test site (how to use an electronic device – monitor for vital signs monitoring, other IT systems) and does not explain different medical activities. Practically, the training material helps the nurse but does not replace the hospital's procedures, protocols and guidelines.

# 8. BIBLIOGRAPHY


Ajzen, I. (1991). The theory of planned behavior. Organizational Behavior and Human Decision Processes, 50(2), 179–211. doi:10.1016/0749-5978(91)90020-T

Boren, M. T., & Ramey, J. (2000). Thinking aloud: Reconciling theory and practice. IEEE Transactions on Professional Communication, 43(3), 261–278. http://doi.org/10.1109/47.867942

Davis, F. (1989a). Perceived usefulness, perceived ease of use, and user acceptance of information technology. MIS quarterly, 13(3), 319–340.

Davis, F. (1989b). User acceptance of computer technology: a comparison of two theoretical models. Management Science, 35(8), 982–1003.

Davis, F. D. (1993). User acceptance of information technology: system characteristics, user perceptions and behavioral impacts. International Journal of Man-Machine Studies, 38(3), 475–487. doi:10.1006/imms.1993.1022

Davis, F. D. F. (1985). A technology acceptance model for empirically testing new end-user information systems: Theory and results. Massachusetts Institute of Technology.

Ericsson, K. A., & Simon, H. A. (1980). Verbal Reports as Data. Psychological Review, 87(3), 215–251. http://doi.org/10.1037/0033-295X.87.3.215

Rigotti, T., Schyns, B., & Mohr, G. (2008). A Short Version of the Occupational Self-Efficacy Scale: Structural and Construct Validity Across Five Countries. Journal of Career Assessment, 16(2), 238–255. http://doi.org/10.1177/1069072707305763

Finstad, K. (2010). The Usability Metric for User Experience. Interacting with Computers 22 (2010) 323–327.

Fishbein, M., & Ajzen, I. (1975). Belief, attitude, intention and behavior: an introduction to theory and research.

Miles, J. & Gilbert, P. (2005). A Handbook of Research Methods for Clinical and Health Psychology. Oxford University Press, Oxford.

Schyns, B., & von Collani, G. (2002). A new Occupational Self-Efficacy Scale and its relation to per- sonality constructs and organisational variables. European Journal of Work and Organizational Psychology, 11, 219-241

Judge, T. A., & Bono, J. E. (2001). Relationship of core self-evaluations trait—self-esteem, gener- alized self-efficacy, locus of control, and emotional stability—with job satisfaction and job per- formance: A meta-analysis. Journal of Applied Psychology, 86, 80-92.

Stajkovic, A. D., & Luthans, F. (1998). Self-efficacy and work-related performance: A meta-analysis. Psychological Bulletin, 124, 240-261.

Hussain, Z., Slany, W., & Holzinger, A. (2009). Current State of Agile User-Centered Design: A Survey. In A. Holzinger & K. Miesenberger (Eds.), HCI and Usability for e-Inclusion: 5th Symposium of the Workgroup Human-Computer Interaction and Usability Engineering of the Austrian Computer Society, USAB 2009, Linz, Austria, November 9-10, 2009 Proceedings (pp. 416-427). Berlin, Heidelberg: Springer Berlin Heidelberg.

Jurca, G., Hellmann, T. D., & Maurer, F. (2014, July 28 2014-Aug. 1 2014). Integrating Agile and User-Centered Design: A Systematic Mapping and Review of Evaluation and Validation Studies of Agile-UX. Paper presented at the 2014 Agile Conference.

Russ, A. L., Baker, D. A., Fahner, W. J., Milligan, B. S., Cox, L., Hagg, H. K., & Saleem, J. J. (2010). A Rapid Usability Evaluation (RUE) Method for Health Information Technology. AMIA Annual Symposium Proceedings, 2010, 702-706.

Schwartz, L. (2013). Agile-User Experience Design: an Agile and User-Centered Process? Paper presented at the Proc. the 8th International Conference on Software Engineering Advances.

Venkatesh, V. (2000). Determinants of perceived ease of use: Integrating perceived behavioral control, computer anxiety and enjoyment into the technology acceptance model. Information Systems Research, 11, 342–365.

Venkatesh, V., & Bala, H. (2008). Technology Acceptance Model 3 and a Research Agenda on Interventions. Decision Sciences 39 (2), p. 273-315.

Venkatesh, V., & Davis, F. (1996). A model of the antecedents of perceived ease of use: Development and test. Decision sciences.

Venkatesh, V., & Davis, F. D. (2000). A theoretical extension of the technology acceptance model: Four longitudinal field studies. Management Science, 46, 186–204.

# ANNEX I (QUESTIONNAIRES)

## A) Sociodemographic Data

Please indicate the following information about yourself in the right column.

| | |
|---|---|
| Year of birth | 19 _ _ |
| Gender | O female O male O rather not say |
| Job role | |
| Job experience in years | _ _ years |
| Working hours per week | _ _ hours |

## B) UMUX (The Usability Metric for User Experience)

Please rate the following statements about the LetItFlow solution on a scale from 1 (Strongly Disagree) to 7 (Strongly Agree).

1. The LetItFlow solutions's capabilities meet my requirements.

1 2 3 4 5 6 7
Strongly Disagree — Strongly Agree

2. Using the LetItFlow solution is a frustrating experience.

1 2 3 4 5 6 7
Strongly Disagree — Strongly Agree

3. The LetItFlow solution is easy to use.

1 2 3 4 5 6 7
Strongly Disagree — Strongly Agree

4. I have to spend too much time correcting things with the LetItFlow solution.

1 2 3 4 5 6 7
Strongly Disagree — Strongly Agree

## C) OSES (Short Version of the Occupational Self-Efficacy Scale)

Please rate the following statements about the LetItFlow solution on a scale from 1 (Not at all true) to 7 (Completely true).

1. I can remain calm when facing difficulties in my job because I can rely on my abilities.

1 2 3 4 5 6 7
Not at all true Completely true

2. When I am confronted with a problem in my job, I can usually find several solutions.

1 2 3 4 5 6 7
Not at all true Completely true

3. Whatever comes my way in my job, I can usually handle it.

1 2 3 4 5 6 7
Not at all true Completely true

4. My past experiences in my job have prepared me well for my occupational future.

1 2 3 4 5 6 7
Not at all true Completely true

5. I meet the goals that I set for myself in my job.

1 2 3 4 5 6 7
Not at all true Completely true

6. I feel prepared for most of the demands in my job.

1 2 3 4 5 6 7
Not at all true Completely true

## D) TAM (Technology Acceptance Model)

Please read the following statements about the LetItFlow system and tick in the appropriate circle to indicate to what extent you agree or disagree with them.

| | | I strongly agree | I agree | I agree somewhat | undecided /neutral | I disagree somewhat | I disagree | I strongly disagree |
|---|---|---|---|---|---|---|---|---|
| PU1 | Using the system improves my performance in my task. | O | O | O | O | O | O | O |
| PU2 | Using the system in my task increases my productivity. | O | O | O | O | O | O | O |
| PU3 | Using the system enhances my effectiveness in my task. | O | O | O | O | O | O | O |
| PU4 | I find the system to be useful in my task. | O | O | O | O | O | O | O |
| PEOU1 | My interaction with the system is clear and understandable. | O | O | O | O | O | O | O |
| PEOU2 | Interacting with the system does not require a lot of my mental effort. | O | O | O | O | O | O | O |
| PEOU3 | I find the system to be easy to use. | O | O | O | O | O | O | O |
| PEOU4 | I find it easy to get the system to do what I want it to do. | O | O | O | O | O | O | O |
| | I could use a mobile application… | | | | | | | |
| CSE1 | …If there was no-one around to tell me what to do as I go | O | O | O | O | O | O | O |
| CSE2 | …if I just had the built-in help facility for assistance | O | O | O | O | O | O | O |
| CSE3 | …if someone showed me how to do it first | O | O | O | O | O | O | O |
| CSE4 | …if I had used similar packages before this one to do the same job. | O | O | O | O | O | O | O |

| | | I strongly agree | I agree | I agree somewhat | undecided /neutral | I disagree somewhat | I disagree | I strongly disagree |
|---|---|---|---|---|---|---|---|---|
| PEC 1 | I have control over using the system. | O | O | O | O | O | O | O |
| PEC 2 | I have the resources necessary to use the system. | O | O | O | O | O | O | O |
| PEC 3 | Given the resources, opportunities and knowledge it takes to use the system, it would be easy for me to use the system. | O | O | O | O | O | O | O |
| PEC 4 | The system is not compatible with other systems I use. | O | O | O | O | O | O | O |
| | The following questions ask you how you would characterize yourself when you use computers. | | | | | | | |
| CPLAY1 | … spontaneous | O | O | O | O | O | O | O |
| CPLAY2 | … creative | O | O | O | O | O | O | O |
| CPLAY3 | … playful | O | O | O | O | O | O | O |
| CPLAY4 | … unoriginal | O | O | O | O | O | O | O |
| CANX1 | Technology does not scare me at all. | O | O | O | O | O | O | O |
| CANX2 | Working with technology makes me nervous. | O | O | O | O | O | O | O |
| CANX3 | Technology makes me feel uncomfortable. | O | O | O | O | O | O | O |
| CANX4 | Technology makes me feel uneasy. | O | O | O | O | O | O | O |
| ENJ 1 | I find using the system to be enjoyable. | O | O | O | O | O | O | O |
| ENJ 2 | The actual process of using the system is pleasant. | O | O | O | O | O | O | O |
| ENJ 3 | I have fun using the system. | O | O | O | O | O | O | O |
| BI1 | Assuming I had access to the system I intend to use it. | O | O | O | O | O | O | O |
| BI2 | Given that I had access to the system, I predict that I would use it. | O | O | O | O | O | O | O |
| BI3 | I plan to use the system in the next n months (when released). | O | O | O | O | O | O | O |

# ANNEX II (TASK-BASED EVALUATION)

**Task 1: Login and Task menu**
"*Please log in to the LetItFlow system with the credentials that were given to you and have a first look at the LetItFlow app.*"

**Task 2: Task Content/ Training**
Internal medical department Seville:
*"Imagine you have to transfer and receive a patient. As you have not done this for a while, you need support in the steps to perform this. The LetItFlow application can help you with this. Try to find this functionality within the LetItFlow app."*

Laboratory Seville:
*"Imagine you have to replace the pipette. As you have not done this for a while, you need support in the steps to perform this. The LetItFlow application can help you with this. Try to find this functionality within the LetItFlow app."*

Neurological department Romania:
*"Imagine you have to prepare the monitor for patient monitoring after angioplasty with stenting. As you have not done this for a while, you need support in the steps to perform this. The LetItFlow application can help you with this. Try to find this functionality within the LetItFlow app."*

**Task 3: Sending Alarm**
*"By using the smartwatch or smartphone, you can send alarms via the LetItFlow application, requesting the help from other employees or warning them about any problem. Please send an alarm to a colleague to ask for support."*

Content of alarm in internal medical department Seville:
*"Mrs E there has been a problem in room 833, the patient in bed 3 has suffered a fall in the bathroom, can you come to help me?"*

Content of alarm in laboratory Seville:
*"I have a mechanical problem in the cobas 8000 1, I do not understand the error message, could you come to help me? Perhaps you know what the problem is please."*

Content of alarm in neurological department Romania:
*"Patient fallen on the floor in room 22 with head injury."*

**Task 4: Receiving Alarm**
[Researcher sends a notification to the smartphone of the test user.]
*"You just received a notification. Please have a look at it and react to the notification."*

Content of alarm in internal medical department Seville:
"Patient from room 27 in bed 2 has an epileptic seizure."

Content of alarm in laboratory Seville:
"I have a mechanical problem in the cobas 8000 1, I do not understand the error message, could you come to help me? Perhaps you know what´s the problem please."

Content of alarm in neurological department Romania:
"Patient from room 27 in bed 2 has an epileptic seizure."

**Task 5: Sending Photo Message**
Internal medical department Sevilla:

*"Imagine you want to inform your colleagues about different types of tubes. Please take a picture of the tubes and send it to your colleagues Susan, Peter and Ulli."*

Laboratory Sevilla:
*"Imagine you want to inform your colleagues that the reagent is exhausted and there is no more in the warehouse, it is necessary to remind the supervisor to urgently claim the order. Please take a picture of the reagent ordering number and send it to your colleagues Susan, Peter and Ulli."*

Neurological department Romania:
*"Imagine you want to inform your colleagues about an error that occurred on the monitor. Please take a picture of the monitor and send it to your colleagues Susan, Peter and Ulli."*

**Task 6: Mentoring**
[The aim of this task is to select the right person needed for the mentoring. The mentoring itself is not part of the task.]
Internal medical department Seville:
"*Imagine you have to do a lumbar puncture. As you have not done this for a while, you need support in the steps to perform this task and would like to know who could help you. Look in the LetApp for someone who has performed the task recently to receive mentoring."*

Laboratory Seville:
"*Imagine you have to replace the pipette. As you have not done this for a while, you need support in the steps to perform this task and would like to know who could help you. Look in the LetApp for someone who has performed the task recently to receive mentoring."*

Neurological department Romania:
"*Imagine you have to do an ECG. As you have not done this for a while, you need support in the steps to perform this task and would like to know who could help you. Look in the LetApp for someone who has performed the task recently to receive mentoring."*

**Task 7: Shift change**
"Imagine you just started your working shift and want to know the relevant information from the previous shift. Let's have a look at it."

Internal medical department Seville:
*"Room 825, bed 2: The diabetic patient had an elevation of his glycaemia above 300 mg / dL which has caused him a crisis that had to be treated with rapid-actin insulin. Glycaemia levels should be checked every hour and adjusted to the diet and the treatment."*

Laboratory Seville:
*"Task 1: Check order status of reagent ACTH*
*Task 2: Check if the ACTH reagent has arrived and process the pending samples in the refrigerator."*

Neurological department Romania:
*"Room 28, bed 4: Patient needs levodopa administration at 7:30-12-15:30-20. You should administer the levodopa treatment!"*

**Task 8: Workflow Management and Inserting a new task**
**For head nurse / head of the laboratory:** "Imagine you want to check the status of the workflow instances for the current shift for your entire team. Please have a look at it and assign a new task to team member Susan with the following text [see below]".
**For nurse / orderly / technician:** "Imagine you are the head nurse / head of laboratory and want to check the status of the workflow instances for the current shift for your entire team. Please have a look at it and assign a new task to team member Susan with the following text [see below]".

Internal medical department Seville:

*"Susan, the patient of bed 2 in room 825 has suffered an elevation of his blood pressure. Please monitor his blood pressure throughout the day."*

Laboratory Seville:
*"Susan, I have reviewed the status of the ALT quality controls and it has been proven that even within the permitted limits, they have an incorrect trend. You can proceed to this before the processing of daily samples."*

Neurological department Romania:
*"Administration of i.v. infusion with Ringer solution after angiography for patient in the room 29, bed 3"*

*Observation: Does the user find the way to the respective functionality in the app? Does he/she need support?*

Interview questions:

1. What is your impression of the LetItFlow application?
2. Which aspects of the features are useful/not useful for you?
3. How clear and reasonable is the procedure of the functionalities to you?
4. Are there any important aspects or information missing?
5. Which features do you think could be of added value to you? Please explain why or why not.
6. Which features do you think would you use during working hours? Please explain why or why not.
7. What do you think about the features in terms of privacy aspects?

# ANNEX III (SEMI-STRUCTURED INTERVIEW GUIDE)

1. Technical issues
    a. As you know, the LetItFlow application is not yet a fully finished and perfectly working technology. Therefore, we would be very interested in hearing things that did not work or did not work properly. Can you tell us about anything that happened over the last days?

2. Changes in work routine
    a. Please think about the last days using the LetItFlow application: did you experience any changes in your daily work routines or activities?

3. Use of Functionalities
    a. Did you use the **task content/training** functionality for support in special tasks?
        i. If yes: Please tell me what happened.
        ii. If yes: What did you think about the information and the way it was presented to you?
        iii. If yes: How useful was this functionality to you?
    b. Did you use the application to **call other colleagues for support**?
        i. If yes: Please tell me what happened.
        ii. If yes: How useful was this functionality to you?
    c. **Did colleagues ask you for support** via the LetItFlow application?
        i. If yes: Please tell me what happened.
        ii. If yes: What did you think about the information and the way it was presented to you?
        iii. If yes: How useful was this functionality to you?
    d. Did you **send messages** to your colleagues to notify them about something?
        i. If yes: Did you use the option to send audio messages or pictures?
        ii. If yes: Please tell me what happened.
        iii. If yes: How useful was this functionality to you?
    e. Did you **receive messages** from your colleagues?
        i. If yes: Please tell me what happened.
        ii. If yes: What did you think about the information and the way it was presented to you?
        iii. If yes: How useful was this functionality to you?
    f. Did you use the **mentoring** functionality?
        i. If yes: Please tell me what exactly happened.
        ii. If yes: How useful was this functionality to you?
    g. Did you use the **shift change** functionality to see the important data from the last shift?
        i. If yes: Please tell me what happened.
        ii. If yes: Whatdid you think about the information and the way it was presented to you?
        iii. If yes: How useful was this functionality to you?
    h. Did you use the **bedside reporting** to note important information of your patients?
        i. If yes: Please tell me what happened.
        ii. If yes: How useful was this functionality to you?

    Questions i. and j. are only directed to head nurses or laboratories:

    i. Did you use the **workflow management** functionality to check the status of the workflow?
        i. If yes: Please tell me what happened.
        ii. If yes: What did you think about the information and the way it was presented to you?
        iii. If yes: How useful was this functionality to you?
    j. Did you use the LetItFlow functionality to **insert new tasks**?
        i. If yes: Please tell me what happened.
        ii. If yes: What did you think about the information and the way it was presented to you?
        iii. If yes: How useful was this functionality to you?

4. **General experiences** with LetItFlow
    a. How did you experience your time with the LetItFlow system?

b. Please tell me about your most positive experiences with LetItFlow.
c. Please tell me about your most negative experiences with LetItFlow.
d. What are your most favorite functions of LetItFlow?
e. In the following please assess / discuss briefly the **impact that you expect LetItFlow to make** with regard to the following aspects (please provide short statements/keywords for each):
    i. Potential of retaining both young and old nurses
    ii. Delaying retirement of older nurses
    iii. Improved compliance
    iv. Improved satisfaction with work conditions
    v. Improved reputation of hospital care
    vi. Improved image and branding

# ANNEX IV (INFORMED CONSENT)

1. Informed Consent used in The University Emergency Hospital Bucharest - Neurology Department
2. Informed Consent used in The Clinical Biochemistry Clinical Management Unit of the Virgen Macarena University Hospital
3. Informed Consent used in The Clinical Biochemistry UGC of the University Hospital Virgen Macarena