Deliverable D4.1

MATISSE pilot set-up & Data Management Plan

MATiSSE

Empower Hospitals' Reliability via TagItSmart Service platform

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Executive Summary

Automation and optimization of medical processes has been decisively backed up via the latest advances in the Internet of Things, cloud computing and analytics. However, “never events” of wrong medication, wrong patients, wrong exams or even surgeries are still recorded, revealing that there is considerable room for improvement. MATISSE aims to minimize the never events within hospitals by automating and rationalizing the processes related to drugs’ stocktaking, delivery to hospitalized patients, medical exams retrieval, surgery preparation and patients’ monitoring.

MATISSE comprises the MATISSE backend platform, the MATISSE mobile application and the MATISSE dashboard, integrated with the MATISSE Smart Cart. The integrated MATISSE framework will be piloted in City Clinic under realistic hospital conditions. During the pilot preparation phase, the following activities have been performed:

- Brief description of the environment and MATISSE tools (both hardware and software), which will be used during the pilot phase
- Test cases’ specification, covering all five MATISSE use cases
- Test report questionnaires’ specification for all five MATISSE use cases
- Development of the project’s Data Management Plan (DMP) to ensure ethical and legal protection of sensitive data. The main goal is to gather information on the MATISSE framework, addressing any legal or ethical issues which might be relevant for the implementations performed in the scope of the MATISSE project.

As a next step, MATISSE will be piloted and results will be processed to evaluate the MATISSE efficacy in reaching the project goals.

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List of Abbreviations

DMP	Data Management Plan
EC	European Commission
FC	Functional Codes
GDPR	General Data Protection Regulation
TTI	Time-Temperature Indicators
QR	Quick Response
WP	Work Package

1. Introduction

The present document constitutes the first deliverable of the Work Package (WP) 4 *MATISSE pilot set-up & Data Management Plan* of the MATISSE project, reporting the activities conducted in the framework of Task 4.1 “Pilot site preparation”. The document reports the preparation activities for the MATISSE pilot in City Clinic, Athens, as well as the project’s DMP.

The rest of the document is organised as follows:

- Section 2 presents the pilot set-up, describing the environment, tools, as well as test cases and reports
- Section 3 provides the DMP
- Section 4 draws conclusions and next steps.

2. Pilot Setup

2.1. Environment

MATISSE will be validated in real life pilot hosted by City Clinic. City Clinic is a newly established private hospital in the heart of Athens. Aiming at promoting high-end health services towards the general population of adults and seniors, it combines medical expertise with state of the art medical technology. The institution focuses on personalized care, taking into consideration individual needs and desires of patients.

City Clinic will provide an ideal environment for the MATISSE pilot, offering four floors of mostly spacious two-bed rooms to a total of sixty beds, clinics, and diagnostic laboratories and a fully equipped surgical floor. Specifically, the MATISSE pilot will take place in the Orthopedics department. City Clinic participates in MATISSE with 2 doctors and 2 nurses for a duration of 10 months.

MATISSE will be validated in a real environment, but no real patients or prescriptions will be involved. Instead of this, “virtual patients” will be considered in potentially free beds of the Clinic. These “virtual patients” will be assigned “virtual prescriptions” and health records through the MATISSE platform. In this way, the pilot conditions will simulate as close as possible the real case with real patients, prescriptions and health records.

2.2. Tools

2.2.1 Hardware

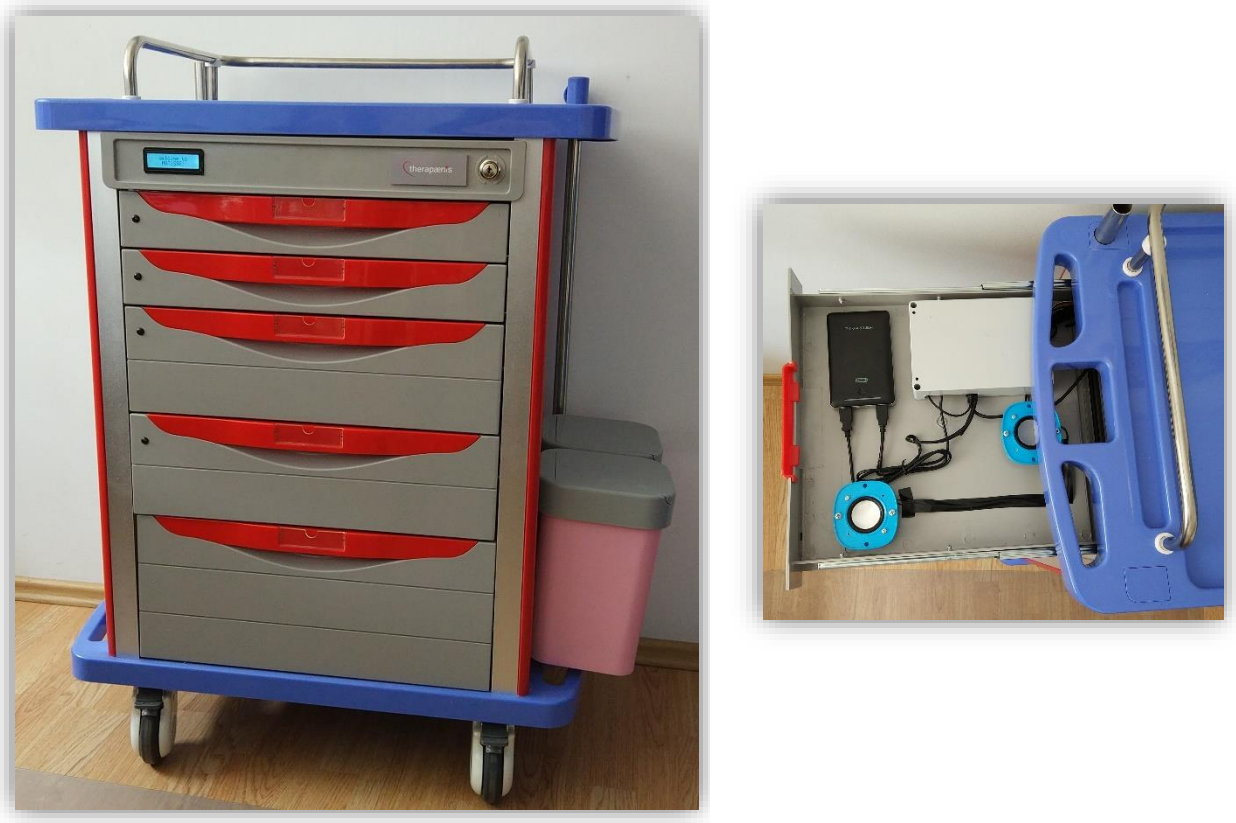
2.2.1.1 Smart Medication Cart

During pilot execution, the smart cart being developed within the framework of MATISSE will be used and validated along with the MATISSE software platform. The MATISSE smart cart will be used during drugs’ stocktaking and distribution to patients. It exposes the following main features:

- Association of drawers and bins to patients, pending for medicine provision
- Light indication of the correct drawer and bin corresponding to the current patient
- Sound notification of wrong drawer opening (not corresponding to the current patient)
- LCD display of useful information (e.g. current patient, current user)
- Communication and integration with the MATISSE mobile app
- Secure communication with the MATISSE backend platform
- 10h of runtime

Within the MATISSE pilot validation, the smart cart will be used to facilitate and automate the process of the drugs’ preparation and distribution to patients, while minimizing potential errors which might occur during these processes.

Figure 1 presents the MATISSE smart cart (a), as well as its supporting devices (b).



(a) *(b)*

Figure 1: The MATISSE smart cart

2.2.1.2 Smart Tags

In this section, the tags which will be used in the MATISSE pilot validation are described. MATISSE will utilize two types of tags; (a) Functional Codes (FCs) in the form of Quick Response (QR) codes, and (b) TTIs sensitive in two threshold temperature values (upper and lower) to ensure that medication is stored between 2 and 8 ^{o}C. The next subsection presents in more detail the MATISSE TTI solution.

2.2.1.2.1 MATISSE Time-Temperature Indicators

2.2.1.2.2 ShockWatch Healthcare Cold Chain Complete

The TTIs which will be used in the MATISSE pilot will be the “Healthcare Cold Chain Complete” offering by ShockWatch, as presented in Figure 2.

Figure 2: ShockWatch Healthcare Cold Chain Complete TTIs

The main characteristics of these TTIs can be summarized as:

- ColdMark – 83.82mm x 20.32mm x 10.16mm
- WarmMark – 45.72mm x 20.32mm x 2.54mm
- Indication Type:
    - ColdMark – Visual, irreversible clear to purple colour change in activation window
    - WarmMark – Visual, irreversible white to red colour change in activation window
- Activation Method: Manual: Peel back of label
- Moisture Resistance: Not suitable for immersion in water
- Product Life: 2 years from date of sale when stored as recommended
- Product Active Life: 6 months provided the full-time period does not exceed 2 years
- Operating Temperature Range (Activated State): +2°C to +8°C
- Activation Temperature Exposure Time Period: 30 mins
- Temperature Accuracy: +/-1°C

Within the pilot, the TTIs will monitor the storage conditions of drugs, which are recommended to be stored between +2°C and +8°C. TTIs will be attached to drugs' packages and will be checked during drugs' collection for the medication cart preparation.

2.2.1.2.3 The MATISSE Combined Tag

During the Medicine Stocktaking use case, medication will be attached both FC and TTIs to provide drug related information and validate proper storage conditions respectively. Although these tags

will be attached adjacent to each other, they will be considered as a combined tag. This combined tag will have the form of the example shown in Figure 3.

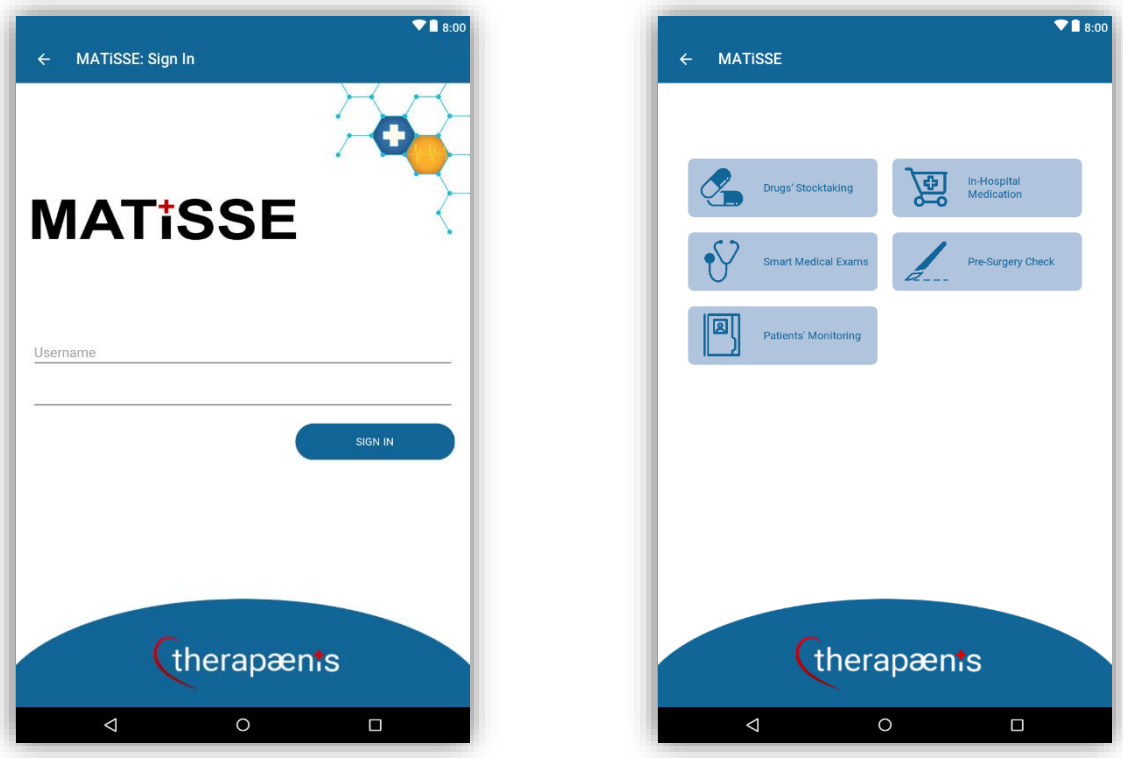
Figure 3: An indicative MATISSE combined tag

Both tag types are scanned using a mobile phone. In the FC case, the mobile phone's scanner will encode the QR code assigned to the current drug, while in the TTI case, the MATISSE mobile app will be able to recognise whether there is a visual indication of temperature thresholds being violated.

2.2.2 Software

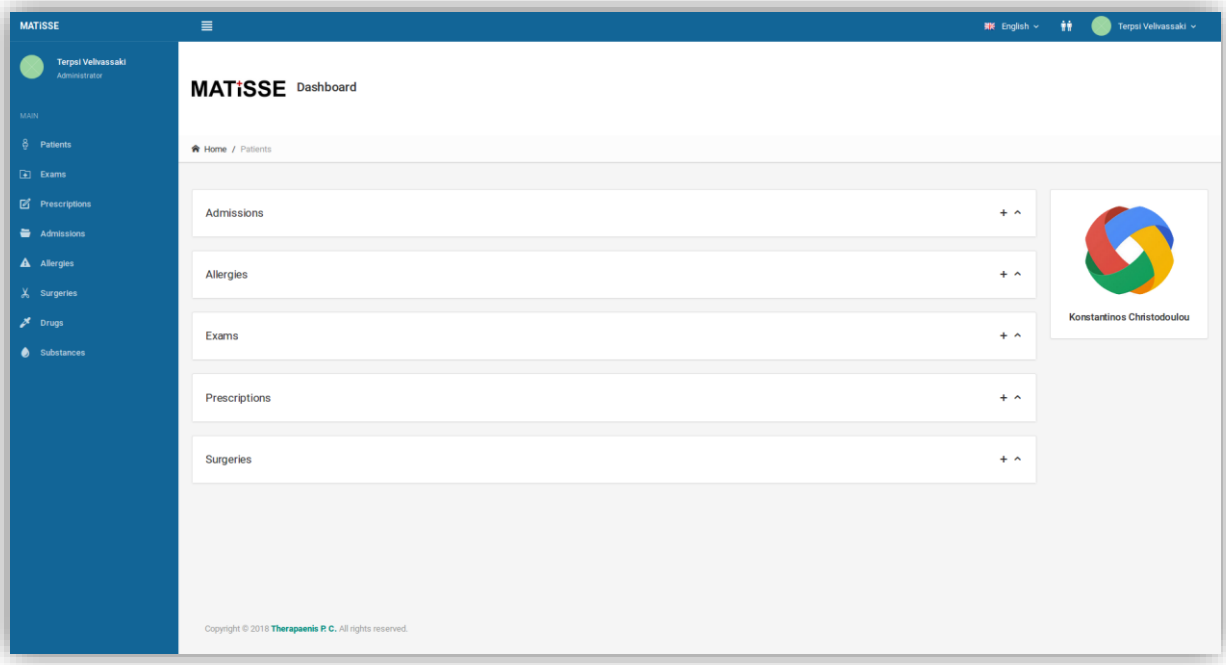
The MATISSE pilot will validate all three pieces of MATISSE software:

- The MATISSE Backend, which provides the MATISSE repository, as well as the platform backend services, such as authentication/authorization, the implementation of the MATISSE semantic model, access to the MATISSE repository, etc.
- The MATISSE Mobile App, which supports the five MATISSE use cases and integrates with the smart cart functionalities. Figure 4 presents the MATISSE mobile app welcome screen (a) and the main menu (b), providing options for the five MATISSE use cases.
- The MATISSE Dashboard, which allows authorized users to insert health data into the MATISSE repository. These data include patients' profiles and health records, as well as drugs list. The MATISSE dashboard is depicted in Figure 5, providing the types of information available for a specific patient, both in English (a) and Greek (b).

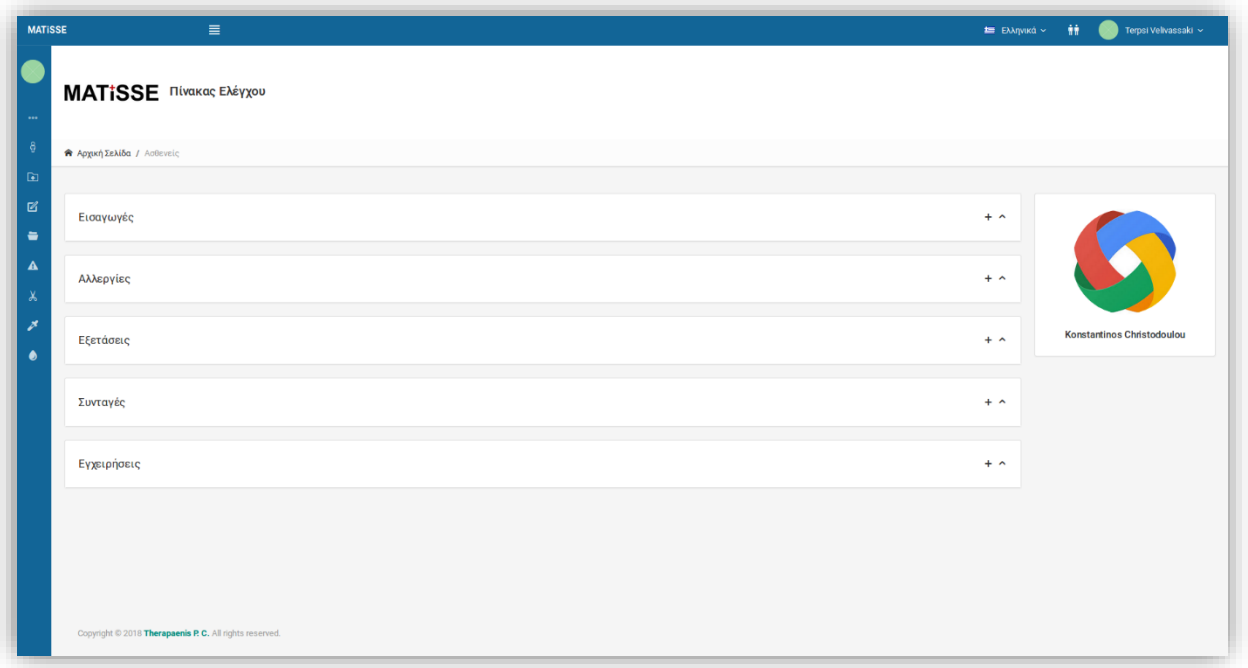


(a) *(b)*

Figure 4: The MATISSE mobile application



(a)



(b)

Figure 5: The MATISSE dashboard, available in both English (a) and Greek (b)

More information about the MATISSE software will be provided in the future MATISSE deliverables "D3.1 MATISSE prototype" and "D3.2 MATISSE Selected Binaries".

2.3. Test Cases

The MATISSE test cases aim at validating the MATISSE platform in each one of the use cases defined in D2.1 "MATISSE system architecture & design" [1], namely:

- Use Case 1: Drugs' stocktaking
- Use Case 2: In-Hospital Medication
- Use Case 3: Smart Medical Exams
- Use Case 4: Pre-surgery Check
- Use Case 5: Patients' Monitoring

The first two use cases listed above will be performed sequentially as they interrelate, while the rest can be performed independently.

2.3.1 Use Case 1: Drugs' stocktaking

In order to validate the first use case, the following prerequisites have to be met:

- At least one smart cart must be available
- An Android tablet or smart phone with the MATISSE mobile app installed must be available
- Both the smart cart and the mobile device must have adequate battery resources at the beginning of the process at the beginning of the process

- Communication between the smart cart, the MATISSE mobile app and the MATISSE backend must be available
- The hospital worker (e.g. nurse) must have a valid account with proper access rights in the Drugs' stocktaking use case
- Both the smart cart and the drugs must be attached with tags with QR codes. For drugs which must be stored cooled (between +2°C and +8°C), drugs' packaging must be attached with smart tags in the form of Time-Temperature Indicators (TTIs), sensitive in two threshold temperature values (upper and lower) to ensure that medication is stored between 2 and 8 ^{o}C.
- A list of patients must be present in the MATISSE data storage
- A list of prescriptions for at least one patient must have been stored in the MATISSE data storage

During validating the "Drugs' stocktaking" use case, a nurse will perform the following steps:

a) Sign in the MATISSE mobile application
b) Select the Drugs' stocktaking option
c) The scanner is activated; the nurse scans the cart
d) The first patient appears with a list of medicine to be provided. At the same time, the led of the respective drawer is on. The nurse opens the drawer. If it is wrong, a sound notifies him/her, so she/he closes it and opens the correct one. If it is correct, the led of the patient's bin is on.
e) The nurse selects a drug from the list in the mobile app, collects the drug (physically) and scans it. If it is wrong, the nurse is notified by the app. Also, the drug's storing conditions are verified through its smart tag in the mobile app. If storing conditions are fine, the drug is removed from the list, otherwise, the app waits for another item to be scanned. The process is repeated until the correct drug under proper storage conditions is collected.
f) The nurse puts the drug in the patient's bin, the led of which is on;
g) Steps e)-f) are repeated until the whole drug list is provided.
h) The nurse visualizes the next patient's medicine list in the mobile app and steps d)-g) are repeated for all patients.
i) When all patients are served, the app returns to the welcome screen and the cart is ready.

2.3.2 Use Case 2: In-Hospital Medication

In order to validate this use case, the following prerequisites have to be met:

- At least one smart cart must be available, already equipped with patients' drugs, following use case 1 process
- An Android tablet or smart phone with the MATISSE mobile app installed must be available
- Both the smart cart and the mobile device must have adequate battery resources at the beginning of the process
- Communication between the smart cart, the MATISSE mobile app and the MATISSE backend must be available
- The hospital worker (e.g. nurse) must have a valid account with proper access rights in the In-Hospital Medication use case

- Both the smart cart, the drugs and the patients must carry tags with QR codes.

During the validation of the "In-Hospital Medication" Use Case, the nurse will accomplish the following steps:

a) Sign-in the MATISSE mobile application
b) Select the In-Hospital Medication option
c) The mobile app's QR scanner is activated and the nurse scans the first patient's tag
d) The patient's data appear in the mobile app screen, including the patient's photo and an overview of the cart's drawers, indicating the drawer where the current patient's drugs are stored. At the same time, the drawer's led is on.
e) The nurse selects the drawer through the app and the position of the current patient's bin appears
f) The nurse opens the drawer of the smart cart, the led of which is on. If she/he opens the wrong drawer, a sound will notify her/him. If she/he opens the correct one, the current patient's bin led is on.
g) The nurse takes the drugs and selects the bin from the app.
h) The bin's led is off
i) Steps b)-h) are repeated until all the patients are provided with their medication.

2.3.3 Use Case 3: Smart Medical Exams

In order to validate this use case, the following prerequisites have to be met:

- An Android tablet or smart phone with the MATISSE mobile app installed must be available
- The mobile device must have adequate battery resources at the beginning of the process
- Communication between the MATISSE mobile app and the MATISSE backend must be available
- The hospital worker (e.g. doctor) must have a valid account with proper access rights in the Smart Medical Exams use case
- At least one patient and at least one associated exam record must be stored in the MATISSE Data Storage
- The patient(s) involved must carry tag(s) with QR codes.

During the validation of this use case, the doctor must follow the steps below:

a) Sign in the MATISSE mobile application
b) Select the Smart Medical Exams option
c) The mobile app QR scanner is activated and the doctor scans the patient's tag
d) The doctor visualizes the list of available exams for the scanned patient, if any, through the mobile app.
e) The doctor selects one medical exam item and visualizes details about it.

2.3.4 Use Case 4: Pre-surgery Check

In order to validate this use case, the following prerequisites have to be met:

- An Android tablet or smart phone with the MATISSE mobile app installed must be available
- The mobile device must have adequate battery resources at the beginning of the process
- Communication between the MATISSE mobile app and the MATISSE backend must be available
- The hospital worker (e.g. doctor or nurse) must have a valid account with proper access rights in the Pre-surgery Check use case
- At least one patient and at least one associated surgery record must be stored in the MATISSE Data Storage. The surgery must be pending and not refer to completed past surgeries.
- The patient(s) involved must carry tag(s) with QR codes.

During the validation of this use case, the doctor or nurse must follow the steps below:

a) Sign in the MATISSE mobile application
b) Select the Planned Surgeries option
c) The mobile app QR scanner is activated and the doctor/nurse scans the patient's tag
d) The doctor visualizes the pending surgery item for the scanned patient, if any, through the mobile app.
e) The doctor selects the surgery item and visualizes details about it to verify that correct surgery process is applied to the current patient.

2.3.5 Use Case 5: Patients' Monitoring

In order to validate this use case, the following prerequisites have to be met:

- An Android tablet or smart phone with the MATISSE mobile app installed must be available
- The mobile device must have adequate battery resources at the beginning of the process
- Communication between the MATISSE mobile app and the MATISSE backend must be available
- The hospital worker (e.g. doctor) must have a valid account with proper access rights in the Patients' Monitoring use case
- At least one patient and at least one associated prescription, exam, surgery, admission or allergy record must be stored in the MATISSE Data Storage.
- The patient(s) involved must carry tag(s) with QR codes.

During the validation of this use case, the doctor must follow the steps below:

a) Sign in the MATISSE mobile application
b) Select the Patients' Monitoring option
c) The mobile app QR scanner is activated and the doctor scans the patient's tag

d) The doctor visualizes the list of prescriptions, exams, surgeries, hospital admissions or allergies for the scanned patient, if any, through the mobile app.

e) The doctor selects any item and visualizes details about it to get informed about the current patient's health record.

2.3.6 Test Reports

The test reports will be provided by the MATISSE pilot participants, using appropriate questionnaires, developed specifically for each pilot scenario or test case. These questionnaires will be collected and processed in order to derive aggregate test results of MATISSE piloting per pilot phase and test case.

The test report questionnaires are provided in the next subsections.

2.3.6.1.1 Use Case 1: Drugs' stocktaking

Drugs' stocktaking – Test Report

	Yes	No
Please tick the appropriate boxes		
Smart cart activation		
Is it easy to activate the smart cart?	☐	☐
How much time does it take for the welcome screen to appear in the smart cart?	☐	☐
mobile app/sign-in		
Is the user able to sign-in with their credentials?	☐	☐
In case the inserted username and/or password are wrong, is the user notified accordingly?	☐	☐
Is it possible to navigate in any app view without signing in?	☐	☐
Is the user automatically signed out after some time of inactivity?	☐	☐
Mobile app/signed-in user		
Is it possible to select the "Drugs' stocktaking" option?	☐	☐
Is the QR scanner automatically activated?	☐	☐
Is it easy to understand that the smart cart has to be scanned?	☐	☐
Is the QR scanning possible?	☐	☐
How much time does it take to for a QR code to be recognized?		

☐ negligible	☐ more than 5''	☐ more than 10''
Does the cart screen display the user and current patient?	☐	☐
Does any patient name appear after the cart scan?	☐	☐
Does the list of drugs for this patient appear?	☐	☐
Is the cart drawer led on?	☐	☐
In case the wrong drawer is opened, does a sound notify the user?	☐	☐
In case the right drawer is opened:		
a) is its led off?	☐	☐
b) Is the bin's led on?	☐	☐
From the drugs' list, can every drug be selected?	☐	☐
Does the scanner open automatically?	☐	☐
How much time does it take to for a QR code to be recognized?		
☐ negligible	☐ more than 5''	☐ more than 10''
Is it easy to understand that the drug has to be scanned?	☐	☐
In case a wrong drug is scanned, is it easy for the user to understand it?	☐	☐
When the correct drug is scanned, does it disappear from the list?	☐	☐
When all drugs are scanned, is it easy for the user to understand that the next patient option should be selected?	☐	☐

Date: _____

Participant Name: _____

2.3.6.1.2 Use Case 2: In-Hospital Medication

In-Hospital Medication – Test Report

	Yes	**No**

Please tick the appropriate boxes

Mobile app/signed-in user

Is it possible to select the “In-Hospital Medication” option?	☐	☐
Is it easy for the user to understand that the patient should be scanned?	☐	☐
Is the QR scanner automatically activated?	☐	☐
Is it easy for the user to understand that the patient should be scanned?	☐	☐
Is the QR scanning possible?	☐	☐

How much time does it take to for the patient’s tag to be recognized?

☐ negligible ☐ more than 5’’ ☐ more than 10’’

Is it easy for the user to understand and verify that the patient’s drugs are in the correct bin?	☐	☐
In the smart cart, is the correct drawer led on (if not already opened)?	☐	☐
In case the wrong drawer is opened, is there a sound notification for the user?	☐	☐
Is the correct bin’s led on?	☐	☐
Is it possible for the user to select/verify the drawer and the bin through the mobile app?	☐	☐
Does the next patient appear?	☐	☐

How many events of wrong drug delivery have been recorded?

☐ None ☐ 1 or 2 ☐ More than 2 and less than 5 ☐ More than 5

Date: _____

Participant Name: _____

2.3.6.1.3 Use Case 3: Smart Medical Exams

Smart Medical Exams – Test Report

	Yes	**No**

Please tick the appropriate boxes

Mobile app/signed-in user

Is it possible to select the “Planned Surgeries” option?	☐	☐
Is the QR scanner automatically activated?	☐	☐
Is the QR scanning possible?	☐	☐

How much time does it take to for the patient’s tag to be recognized?

☐ negligible ☐ more than 5’’ ☐ more than 10’’

In case there are exams for the patient, is information provided?	☐	☐
In case there are no exams for the patient, is the user notified accordingly?	☐	☐
Is it possible to scan a smart exam?	☐	☐
How long does it take to scan a smart exam tag?	☐	☐

☐ negligible ☐ more than 5’’ ☐ more than 10’’

How many events of wrong association of exams to patients have been recorded?

☐ None ☐ 1 or 2 ☐ More than 2 and less than 5 ☐ More than 5

Date: _____

Participant Name: _____

2.3.6.1.4 Use Case 4: Pre-surgery Check

Planned Surgeries – Test Report

	Yes	No
Please tick the appropriate boxes		
Mobile app/signed-in user		
Is it possible to select the “In-Hospital Medication” option?	☐	☐
Is the QR scanner automatically activated?	☐	☐
Is the QR scanning possible?	☐	☐

How much time does it take to for the patient’s tag to be recognized?

☐ negligible ☐ more than 5’’ ☐ more than 10’’

In case there are planned surgeries for the patient, is information provided?	☐	☐
In case there are no exams for the patient, is the user notified accordingly?	☐	☐

How many events of wrong surgery have been recorded?

☐ None ☐ 1 or 2 ☐ More than 2 and less than 5 ☐ More than 5

Date: _____

Participant Name: _____

2.3.6.1.5 Use Case 5: Patients' Monitoring

Patients' Monitoring – Test Report

	Yes	No
Please tick the appropriate boxes		
Mobile app/signed-in user		
Is it possible to select the "Patients' Monitoring" option?	☐	☐
Is the QR scanner automatically activated?	☐	☐
Is the QR scanning possible?	☐	☐

How much time does it take to for the patient's tag to be recognized?

☐ negligible ☐ more than 5'' ☐ more than 10''

In case there is information for the patient, is this provided?	☐	☐
Is this information correctly displayed?	☐	☐
In case there are no records for the patient, is the user notified accordingly?	☐	☐

How many events of wrong patient's history retrieval have been recorded?

☐ None ☐ 1 or 2 ☐ More than 2 and less than 5 ☐ More than 5

Date: _____

Participant Name: _____

3. Data Management Plan

3.1. General Information

3.1.1 Introduction

The Data Controller, according to General Data Protection Regulation (GDPR) [2] Art. 4 definitions, is Therapaenis P.C. The Data Controller is the unique responsible for the accuracy, integrity and quality of its own data.

The Data Processor according to GDPR Art. 4 definitions, is Therapaenis P.C, who on behalf of the Data Controller will be in charge of data 'processing' in the sense of GDPR Art.4.

3.1.1.1 Presentation and Responsibilities

Parameter	Description
Product/Service Name	MATISSE
Purpose of the data collection/generation and processing	Provision, maintenance and improvement of the services of the MATISSE Platform.
Does the data collection/ generation and processing involve	Human participation for data collection ☐ No ☒ Yes – if yes please complete §3.1.3
	Patients for data collection: ☒ No ☐ Yes
	Personal Data ☐ No ☒ Yes
	Sensitive Personal Data ☒ No ☐ Yes
Does your product/service involve physical interventions on the study participants?	☒ No ☐ Yes
Does your product/service involve processing of Genetic information?	☒ No ☐ Yes
Does your product/service involve tracking or observation of participants (e.g. surveillance or localization data, and Wan	☒ No ☐ Yes

data, such as IP address, MACs, cookies etc.)?	
Does the Product/Service use connection to existing database?	☒ No ☐ Yes if yes please provide details (name, purpose, means...)
Does the Product/Service use subcontractors?	☒ No ☐ Yes i.e. is the processing/service (or parts of it) provided by external (outside the project) providers? If yes, please provide details in §0.

3.1.1.2 Objectives and Expected Implementations

Parameter	**Description**	
Implementation(s) of the Product/Service in the project	**Implementation purpose** ☒ Preliminary tests ☒ Validation and performance assessment ☒ Demonstration(s) for project dissemination ☒Pre-production implementation(s) for results exploitation ☐ Production implementation(s) for results exploitation	**Implementation location** ☒ EU ☐ other (please provide detail)

3.1.1.3 Specific requirements to fulfil

The following table details the specific "national/funder/sectorial/departmental regulation/procedure" that MATISSE has to fulfil, in case it is applied on real patients. So, these requirements are relevant for a production implementation and following validation/piloting, which are out the scope the MATISSE project. However, there are included here as requirements which will be considered during production implementation in the post project period.

Parameter	**Description**
National requirements	• Act 2071/1992 (NHS) establishment of National Council of Medical Ethics and Deontology • Data Protection Act 2472/1997 • Act 2667/1998: National Bioethics Commission • Act 2619/1998: ratification of the Oviedo Convention • Ministerial Decision DYG3/89292/31.12.2003 (incorporating Directive 2001/20/EE into domestic law) • Act 3418/2005 Code of Medical Ethics and Deontology
European Commission requirements (ie FAIR requirements)	• Article 8 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) • Article 8 of the EU Charter of Fundamental Rights • Directive 95/46/EC (applies until 24th May 2018)

	• Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (applies from 25th May 2018)
Sectorial requirements	-
Departmental requirements	-
Other requirements	-
Submission to Data Protection Officers (Product/Service DPO + Project DPO)	[Will be required if real data are collected, stored and retrieved]
Submission to Data Protection Authorities	Hellenic Data Protection Authority

3.1.2 General view of datasets and processing

3.1.2.1 Introduction

The MATISSE pilot will involve electronic datasets, which will constitute virtual data generated for the sake of the validation, as well as a short dataset in written form, referring to the Participants' data collected during the recruitment or the test reporting phase. Brief dataset description is listed in Appendix A, while more details are provided in the next subsection. The electronic datasets will be processed as described in the table of section 3.1.2.3, while the paper datasets will be handled as described later in the same section.

3.1.2.2 Dataset(s) description

For the sake of validation and with the aim of not disturbing current hospital processes, "virtual" patients' accounts will be created, which will represent the patients whose medicine and hospital stay will be managed through the MATISSE platform. It has to be noted that these accounts will not refer or connect to existing patients in any way, but will only be created for validating the MATISSE platform.

The next tables describe the datasets which be created for the MATISSE pilot and processing applied upon them.

Table 1: Patients' Dataset description

Parameter	Description
Categories of data	Profile data
Type of data	Database contents
Format of data	Text, Numerical
Standards for data and metadata	-
Origin of data	Data will be generated by the user, using the MATISSE dashboard

Volume max	<1GB
Size	<1GB
Security procedure (storage, protection, retention and destruction)	Data will be transferred via encoded communication channels and stored in dedicated servers in Therapaenis premises. Data retrieval is possible only for authorized users.
Other requirements	-
Utility and reuse	only for validation purposes within MATISSE pilot

The Drugs' dataset will be created by the user using the MATISSE dashboard. As the MATISSE pilot is meant for validation of the MATISSE functionalities, no real drugs will be used. Instead of this, fake drug names will be used, which will not relate in any way with real drugs or pharmaceutical products.

Table 2: Drugs' Dataset description

Parameter	Description
Categories of data	Medical
Type of data	Database contents
Format of data	Text, Numerical
Standards for data and metadata	-
Origin of data	Data will be generated by the user, using the MATISSE dashboard
Volume max	<1GB
Size	<1GB
Security procedure (storage, protection, retention and destruction)	Data will be transferred via encoded communication channels and stored in dedicated servers in Therapaenis premises. Data retrieval is possible only for authorized users.
Other requirements	-
Utility and reuse	only for validation purposes within MATISSE pilot

The Health Records' dataset will be generated by the user of the MATISSE dashboard and will represent health records of the "virtual" patients, including prescriptions, medical exams, hospital admissions, surgeries and allergies. As such, the Health Records' dataset will be generated only for validation purposes and will not refer to real surgeries of real patients.

Table 3: Health Records' Dataset description

Parameter	Description
Categories of data	Medical
Type of data	Database contents
Format of data	Text, Numerical

Standards for data and metadata	-
Origin of data	Data will be generated by the user, using the MATISSE dashboard
Volume max	<1GB
Size	<1GB
Security procedure (storage, protection, retention and destruction)	Data will be transferred via encoded communication channels and stored in dedicated servers in Therapaenis premises. Data retrieval is possible only for authorized users.
Other requirements	-
Utility and reuse	only for validation purposes within MATISSE pilot

Table 4: Participants' Dataset description

Parameter	Description
Categories of data	Profile data
Type of data	Database contents
Format of data	Text, Numerical
Standards for data and metadata	-
Origin of data	Data will be provided by the participants during the recruitment and/or test report phase.
Volume max	10 participants' data maximum
Size	N/A
Security procedure (storage, protection, retention and destruction)	Data will be securely stored in the Therapaenis premises as locked confidential documents.
Other requirements	-
Utility and reuse	only for reporting purposes within MATISSE pilot

3.1.2.3 Processing description

The data processing procedures which may be applied on the electronic datasets (Patients', Drugs' and Health Records' datasets) are provided in Table 5, while processing procedures for the Participants' data, which will be provided in paper, are also provided in the rest of this subsection.

Table 5: Processing description for the Patients', Drugs' and Health Records' datasets

Parameter	Description
Name of the software / Application and type of	The above datasets will be generated via the MATISSE dashboard and will be stored in the MATISSE repository. These data can be

platform (e.g. Mobile Apps, SaaS, License)	retrieved only via the MATISSE dashboard or the MATISSE mobile application by authorized users.
If the processing/service (or parts of it) is provided by external providers,	N/A Please precise for each supplier: Name of the supplier Where are the provider' processing activities located? ☐ EU ☐ Non-EU

Moreover, regarding the Participants data (names) which may be provided during the recruitment or reporting phase, will be anonymized when used in electronic form. Indicatively, instead of participants' real data, "Participant X" term may be used to refer to their report, unless explicit consent is given for using the real data by the Participant themselves.

3.1.3 Human participation for data collection

The human research participants who will participate in the MATISSE pilot in City Clinic include hospital staff, such as doctors, nurses or other personnel acting as Prescription Handlers, Medication Distributors, Medical Exams Handlers or Surgery Preparation Handlers. Human participants are adequately informed about the project objectives and procedures, their rights and responsibilities upon acceptance to participate through the Project Information Sheet, which will be provided to them during the recruitment procedures. In this way, participation in the MATISSE pilot will be possible only after candidate participants signed their informed consent for participation in MATISSE pilot activities.

The "Informed Consent Form for data collection and/or data re-use" and the "Project Information Sheet" are provided in Appendix B and C, respectively.

3.1.4 Dataset preparation

Table 6: Preparation information for the used datasets

Parameter	Description
Existing data being re-used?	☒ No ☐ Yes
Are there any ethical or legal issues that can have an impact on data sharing?	☐ No ☒ Yes Ethical or legal issues might be relevant only on Participants' data sharing.
Is informed consent for data sharing and long-term preservation included in questionnaires dealing with personal data?	☐ No ☒ Yes
Re-use – description of treatments (such as pseudo anonymization, anonymization, data	N/A for the datasets referring to "virtual" patients, health records and drugs and will not be publicly available.

transfer between countries, …)	Anonymization will be applied to Participants' data, unless their written consent is given for using their real names.
Production of synthetic data	-
Simulation of specific type of data (stream …)	-
Others	-

3.1.5 Notification by the Data Protection Authorities

No notification to Data Protection Authorities is required, as no real data will be used for patients and health records.

3.1.6 Security procedures

N/A, as no real data will be used for patients and health records.

4. Conclusions

The current report describes the pilot preparation of the MATISSE project. The main goals of this pilot are the validation of the MATISSE functionalities, its usability by the hospital personnel, as well as its efficacy in achieving the project goals. To this end, test cases specification has been elaborated to include all MATISSE functionalities, while specific questionnaires for each use case have been developed, aiming to collect users' feedback about potential malfunctions or improvements and finetuning which could be applied.

Moreover, as MATISSE targets the hospital environment and will involve the management of personal or sensitive, a DMP has been developed, which addresses ethical and legal requirements which may arise. The DMP includes general information about the type of data and planned implementations and specific requirements, as well as the datasets' and processing descriptions. Moreover, procedures for the participation and recruitment of human participants is detailed, while informed consent form and project information sheet have been developed for this purpose.

Following the procedures described in this document, MATISSE will be piloted in City Clinic, while pilot results are expected to be released by the end of the project.

References

[1] MATISSE, "MATISSE System Architecture & Design," H2020 TagItSmart/MATISSE Deliverable Report, 2017.

[2] European Union, "General data protection regulation - (EU) 2016/679," 2016.

Appendix A. List of Data Sets – General view

Datasets Parameter Dataset Id	Description	Data Categories	Types/formats	Origin	Volume	Size	Security features
PILOT_DATA_01	Patients	Profile data	Text, Numerical	Generated by the user - MATISSE dashboard	<1GB	<1GB	Encoded communication channels; Storage in dedicated servers; Data retrieval only by authorized users.
PILOT_DATA_02	Drugs	Medical	Text, Numerical	Generated by the user - MATISSE dashboard	<1GB	<1GB	Encoded communication channels; Storage in dedicated servers; Data retrieval only by authorized users.
PILOT_DATA_03	Health records	Medical	Text, Numerical	Generated by the user - MATISSE dashboard	<1GB	<1GB	Encoded communication channels; Storage in dedicated servers; Data retrieval only by authorized users.
PILOT_DATA_04	Participants	Profile data	Text, Numerical	Informed Consent Form; Test reports	Max 10 participants	N/A	Locked; Destroyed after the project end

Appendix B. Informed Consent Form for data collection and/or data re-use

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Data Handling Information Consent Form

	Yes	No
Please tick the appropriate boxes		
Taking Part		
I have read and understood the project information sheet dated DD/MM/YYYY.	☐	☐
I have been given the opportunity to ask questions about the project.	☐	☐
I agree to take part in the project. Taking part in the project may include being interviewed and recorded (audio or video).	☐	☐
I understand that my taking part is voluntary; I can withdraw from the pilot at any time and I do not have to give any reasons for why I no longer want to take part.	☐	☐
Use of the information I provide for this project only		
I understand my personal details such as phone number and address will not be revealed to people outside the project.	☐	☐
I understand that anonymized data may be quoted in publications, reports, web pages, and other research outputs.	☐	☐
Please choose one of the following two options:		
I would like my real name to be used in the above.	☐	
I would **not** like my real name to be used in the above.	☐	
Use of the information I provide beyond this project		
I agree for the data I provide to be archived at the data repository selected by MATISSE.	☐	☐
I understand and agree that other authenticated researchers may have access to these data only if they agree to preserve the confidentiality of the information as requested in this form.	☐	☐
I understand and agree that other authenticated researchers may use my words in publications, reports, web pages, and other research outputs, only if they agree to preserve the confidentiality of the information as requested in this form.	☐	☐
Consent Certification		
I agree to assign the copyright I hold in any materials related to this project to [name of researcher].	☐	☐

_____	_____	_____
Name of participant	Signature	Date
_____	_____	_____
Name of Researcher	Signature	Date

Appendix C. Project Information Sheet

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Information Sheet

Introduction
My name is [Name of Researcher] and I am working on MATISSE, a system which aims to minimize unacceptable errors which lead to never events within hospitals. MATISSE comprises a smart medication cart, coupled with the MATISSE mobile application, the MATISSE dashboard and the MATISSE backend platform, which automate the processes of smart cart preparation with drugs, their distribution to patients, the confirmation of smart medical exams and pending surgeries, as well as doctors' access to patient's history. MATISSE is going to be piloted in your hospital, so we would greatly appreciate your participation in this pilot as a [doctor/nurse].

Purpose of the pilot
The MATISSE pilot aims to test and validate the MATISSE functionalities within a hospital environment and evaluate the added benefits for both the patients, the personnel and the hospital. So, we aim to ensure that MATISSE operates correctly in everyday operation, offers a useful toolset to both doctors and nurses and adds no overhead compared to existing procedures. Moreover, we would like to collect any useful feedback from the medical professionals which can exploited to improve and/or fine-tune our platform.

Type of Pilot Intervention
The type of intervention of MATISSE will be "complex" in the sense the pilot involves the deployment of a new procedure in the health service or in hospital practice, and, thus, may involve consideration of several interacting components, including, for example, educational components and behavioural change.

Participant Selection
The active participants in the MATISSE pilot are nurses and doctors, who are involved in equipping the medical cart with the drugs to be provided to patients as well as their delivery to them, in exams' search, surgery preparation and common patients' monitoring.

Voluntary Participation
Participation in the MATISSE pilot is voluntary and participants can withdraw at any stage, without having to explain their reasons for withdrawal. However, as early notification of withdrawal as possible, will be appreciated.

Procedures

During validating the "Drugs' stocktaking" use case, a nurse will perform the following steps:

a) Sign in the MATISSE mobile application
b) Select the Drugs' stocktaking option
c) The scanner is activated; the nurse scans the cart

d) The first patient appears with a list of medicine to be provided. At the same time, the led of the respective drawer is on. The nurse opens the drawer. If it is wrong, a sound notifies him/her, so she/he closes it and opens the correct one. If it is correct, the led of the patient's bin is on.

e) The nurse selects a drug from the list in the mobile app, collects the drug (physically) and scans it. If it is wrong, the nurse is notified by the app. Also, the drug's storing conditions are verified through its smart tag in the mobile app. If storing conditions are fine, the drug is removed from the list, otherwise, the app waits for another item to be scanned. The process is repeated until the correct drug under proper storage conditions is collected.

f) The nurse puts the drug in the patient's bin, the led of which is on;

g) Steps e)-f) are repeated until the whole drug list is provided.

h) The nurse visualizes the next patient's medicine list in the mobile app and steps d)-g) are repeated for all patients.

When all patients are served, the app returns to the welcome screen and the cart is ready.

During the validation of the "In-Hospital Medication" Use Case, the nurse will accomplish the following steps:

a) Sign-in the MATISSE mobile application

b) Select the In-Hospital Medication option

c) The mobile app's QR scanner is activated and the nurse scans the first patient's tag

d) The patient's data appear in the mobile app screen, including the patient's photo and an overview of the cart's drawers, indicating the drawer where the current patient's drugs are stored. At the same time, the drawer's led is on.

e) The nurse selects the drawer through the app and the position of the current patient's bin appears

f) The nurse opens the drawer of the smart cart, the led of which is on. If she/he opens the wrong drawer, a sound will notify her/him. If she/he opens the correct one, the current patient's bin led is on.

g) The nurse takes the drugs and selects the bin from the app.

h) The bin's led is off

Steps b)-h) are repeated until all the patients are provided with their medication.

During the validation of this use case, the doctor must follow the steps below:

a) Sign in the MATISSE mobile application

b) Select the Smart Medical Exams option

c) The mobile app QR scanner is activated and the doctor scans the patient's tag

d) The doctor visualizes the list of available exams for the scanned patient, if any, through the mobile app.

The doctor selects one medical exam item and visualizes details about it.

During the validation of “Surgery Preparation” use case, the doctor or nurse must follow the steps below:

a) Sign in the MATISSE mobile application
b) Select the Planned Surgeries option
c) The mobile app QR scanner is activated and the doctor/nurse scans the patient’s tag
d) The doctor visualizes the pending surgery item for the scanned patient, if any, through the mobile app.

The doctor selects the surgery item and visualizes details about it to verify that correct surgery process is applied to the current patient.

During the validation of “Patient’ Monitoring” use case, the doctor must follow the steps below:

a) Sign in the MATISSE mobile application
b) Select the Patients’ Monitoring option
c) The mobile app QR scanner is activated and the doctor scans the patient’s tag
d) The doctor visualizes the list of prescriptions, exams, surgeries, hospital admissions or allergies for the scanned patient, if any, through the mobile app.

The doctor selects any item and visualizes details about it to get informed about the current patient’s health record.

In any case, the participants will be asked to fill in a questionnaire relevant to the correct operation of MATISSE, its usability and its effectiveness in minimizing never events within hospitals. These questions are Yes/No or multiple-choice.

In the test report questionnaire, the only personal data which participants may be asked to provide is their name.

Duration
Each participant will be asked to test MATISSE for a maximum period of one month. After the end of their participation, participants may be asked to provide additional feedback within two weeks.

Risks
No risks are involved for the participants.

Benefits
The execution of the MATISSE pilot will provide useful feedback to validate the functionalities of the platform, as well as finetune and improve it, according to the needs and desires of the real hospital environment and personnel. The optimization of the MATISSE platform will yield a valuable tool for the hospital, its personnel and eventually the patients, leading to minimizing the human or other accidental, yet unacceptable, errors with severe or even fatal effects.
Indeed, the participation in the MATISSE pilot will provide further benefits to individuals, expanding their knowledge of expertise and cultivating a culture of process automation and error prevention among the medical professionals.

Reimbursements
As MATISSE pilot will be conducted in participants' workplace during working hours, no special reimbursements are foreseen.

Confidentiality
All the information collected about you during the course of the pilot will be kept strictly confidential. You will not be able to be identified or identifiable in any reports or publications. Any data collected about you in the questionnaires will be securely stored online or in paper.
Data collected may be shared in an anonymised form to allow reuse by the research team and other third parties. These anonymised data will not allow any individuals to be identified or identifiable.

Certificate of Consent
I have read the provided information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent to participate in the MATISSE pilot.

_____	_____	_____
Name of participant	Signature	Date
_____	_____	_____
Name of Researcher	Signature	Date

Thank you for taking part in the MATISSE pilot.