CAPABLE

Cancer Patients Better Life Experience

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[Interim report on system performances, usage and technical improvements]

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Table of contents

1 Executive Summary

This document presents an interim report on the usage and technical performance of the system. In particular, we present an analysis of the data that are present on the CAPABLE Data Platform and that can be considered as a proxy of the system usage during the pilot study. We discuss the activities of the CAPABLE system components and the differences that have been identified in the two clinical centers where the system is deployed. In addition, we report on the main technical issues that have been found and addressed during the first months of the study, together with a summary of the improvements performed. The analyses presented in this report are based on data extracted from the first deployment of the system at the hospital to June 30th 2023.

2 Introduction

In this document, we present a preliminary report on the CAPABLE system performance and usage during the pilot clinical studies. Studies are ongoing at ICSM Pavia and Policlinico di Bari in Italy, and at NKI in The Netherlands. The provided analysis is intended to present a technical overview on how much the system is currently being used by the final users and to highlight the technical issues and improvements that took place in the first months of the study. The clinical evaluation of the results will be presented at the end of the study and it will be the subject of deliverables D7.8 and D7.10 due on M48.

As of June 30th, a total of 45 patients were contacted in Italy, and consequently we were able to

enrol 16 patients in Pavia and 22 in Bari, for a total of 38 subjects (enrollment rate 84.4%). Around 50 patients were screened for eligibility at NKI. Of those, 23 patients were considered eligible and contacted. Eventually, 16 patients were included in the study and enrolled (enrollment rate 70%). Two patients dropped out in Bari, and no patients dropped out in NKI nor in Pavia.

In Italy, reasons for not participating in the study were mainly related to the technological skills that the patients who were contacted perceived to be necessary to use the system. Reasons for drop-outs were related to lack of time to update the system with the requested data and frustration due to technical defects shown by some smartwatches in battery charging.

In NKI, reasons for non-eligibility included start of targeted therapy (exclusion criteria), decision not to start treatment, treatment in a different centre, or considered to be not mentally suitable for participation by the treating specialist. The 7 contacted patients who did not provide consent to participate gave the following reasons: provided no reason/no informed consent (3/7), too (mentally) burdensome (3/7), or no trust in privacy regulations of their own data/data to be shared (1/7)

The total number of purchased devices was as follows:
- Italy: 28 smartphones, 28 SIM with data traffic and 35 Asus smartwatches
- NKI: 11 smartphones (so far) and 27 Asus smartwatches

The different number of smartphones and smartwatches purchased is due to the fact that some Italian patients choose to use their own telephone.

During the pilot study, the following data, useful for evaluating the usage of the system, are collected in the CAPABLE Data Platform (DP):
- symptoms reported both by the patients through the CAPABLE app and by doctors using the dashboard
- responses to questionnaires administered through the CAPABLE app
- execution of virtual capsules
- messages exchanged among the components, which fall in these categories:
  - from the VC to the patient app or the physician dashboard (advices to the patient or suggestions for the doctors)
  - from PDSS (Physician Decision Support System) to the physician dashboard (guidelines recommendations)
  - technical communications among components
- drug prescriptions, either ordered by the doctor or suggested by the system according to the guidelines
- recommendations accepted and refused by the patient or the doctor.

Besides data collected in the DP, we have set-up other ways to collect technical information useful to analyse the performance of the system and possible bugs and malfunctioning. These are listed in the following:
- bug reporting file, to be used by the technical contact points at the hospitals to report issues to the developers
- components service status monitoring, using logs automatically collected by the Case Manager (CM) to which any other component regularly interacts using a long polling technique
- monitoring of smartwatch usage through daily reports
- diary of the interactions between the system users and the technical contact points at the

hospital
- follow-up questionnaires filled in by the CAPABLE users at 3 months from enrollment, where it is possible to report the technical issues detected during the system usage and the level of satisfaction on the received technical support.

In the following of this report we will present an analysis of the data listed above and collected from the beginning of the study (different for the three centres) until June 30th 2023.
For the studies running in Italy, each component of the CAPABLE system is deployed on a Virtual Machine (VM) provided by ICSM hospital, who acts as the reference partner for Policlinico di Bari in the project. In this way, both the Italian studies use the same system and the data are stored on a unique DP located at ICSM. These VMs are accessible inside ICSM internal network under hospital security policies and rules. Dedicated access to the system is provided, regulated, and managed by ICSM IT staff via suitable networking rules. These allow oncologists at Policlinico di Bari to reach the system in a secure way.

3 Preliminary report on system usage

For analysing the system usage, we have considered both the data collected in the DP and the data collected via the Asus smartwatches that are given to the patients together with the CAPABLE app. Table 1 shows a snapshot of the total number of resources stored in the DP as of June 30th 2023. The results shown in the table were achieved in two separate ways for ICSM and NKI. For ICSM, since we already got clearance by the clinic management to download a pseudonymized data-set for offline operation, we used the procedure illustrated in the subsequent Section 3.1. More specifically we entirely operated on the exported MySQL database where all the computations were accomplished offline issuing structured queries. For NKI instead, since we have not yet received clearance to download a pseudonymized data-set we accomplished every computation online. More specifically we connected directly to the DP through a VPN and manually issued FHIR queries collecting their responses and computing the results.

Table 1 - overall count of resources in the DP as of June 30th 2023

Resource	Number of instances Italy	Number of instances NKI
Observation	169127	10301
MedicationRequest	561	1321
Communication	159048	10154
ServiceRequest	63	15
QuestionnaireResponse	654	154
Goal	64	2
Appointment	88	161

Total	329605	22108

This high level snapshot already points out that the activity of the system in Italy is much more intense than that of the system in NKI. This is for sure due to the number of patients that is, at the moment, more than double in one centre with respect to the other, but also, as we will see in the following, for the fact that patients in NKI are in general experiencing less events than the ones in ICSM, and this causes less activities in the system.

3.1 Data extraction form the DP

During the pilot studies, any data concerning CAPABLE is stored on the DP deployed at each of the two clinical institutions involved: ICSM and NKI. Those data include externally generated data such as those entered by the Patient through the smartphone or by the clinic staff through the dashboard. However they also include a lot of information generated internally by the CAPABLE system representing either communications exchanged by the components as well as output messages to be displayed by Patients and Doctors. Performing an interim analysis of the system performance and usage required accessing and processing all this information. However, in compliance with the security and privacy policies of the clinics enrolling patients for the pilot studies this information is strictly confined within their Intranets where the whole CAPABLE platform is deployed. Moreover, as a policy design choice, we did not want to operate directly on the DPs hosting the live patient data since there is always a risk of negative impact in terms of slowing down their responsiveness or accidentally dropping some data. Finally, working directly on the production DP there is also a high chance of coming across patient sensitive data and not all the people actually analysing the CAPABLE system had the required clearance to access them.

To overcome this issue and allow the accomplishment of some analyses on the two running instances of CAPABLE, we designed an Extraction Tool that is periodically run against the DP of the two clinics and exports the required data to a different database. More specifically, in Figure 1 we show the pipeline we have adopted for this task. The Extraction Tool is run on a separate machine that is temporarily connected through a VPN link to the Intranet of the clinic hosting the DP. Instead of directly querying the native RDBMS of the DP, the Extraction Tool uses the very same FHIR syntax adopted by all the components. This is both helpful as a safety measure to prevent the execution of dangerous queries, but it is also effective in testing the performance of the DP itself.
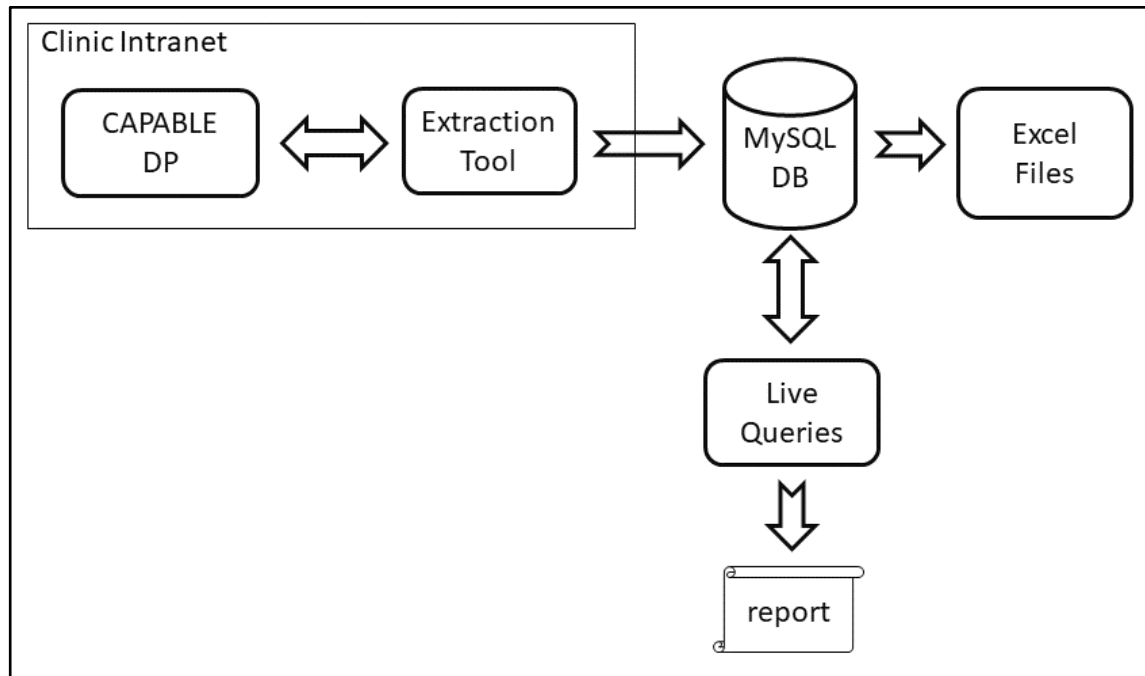
Figure 1. The workflow adopted for extracting data from the DP at the pilot sites.

Data are selected for extraction based on a set of criteria that were deemed useful for the subsequent analysis. The resources collected are then stored on a MySQL database where Live Queries can be performed. Those are useful for computing generic statistics as well as for detecting specific usage patterns of the CAPABLE system. For instance, based on those queries we were able to generate the data included in this deliverable. Nevertheless, all the data available in the MySQL database are also saved on a set of MS Excel files, making them available to all the authorised CAPABLE partners for their own inspection. Finally, data extraction is accomplished incrementally on a monthly basis, which helps in regularly monitoring the use of the CAPABLE system.

As a final remark, it is worth noticing that the code of the Extraction Tool takes special care of eliminating any personal information associated with the resources. More specifically we did not extract the Patient resource altogether since it includes the most part of sensitive information such as patient demographic data or even their phone numbers. Thus, for our analytical purposes data are linked to patients just using the code assigned during the enrollment process. Moreover in extracting the resources referenced in the following tables (see Table 2) we only exported codified data, purposely avoiding any textual representation (i.e. the FHIR "display" fields) where some personal information could have made its way into.

3.2 Analysis of the extracted resources

The FHIR Resources extracted through the process described in Section 3.1 are the following:
- Observation: mainly include data on symptoms (type and severity), executed capsules (i.e., psychological wellbeing, non-pharmacological interventions), recommendations accepted and refused, clinical conditions of the patient (e.g. type of cancer).
- MedicationRequest: are used to report medications. These can be either entered through the

CAPABLE dashboard by the oncologists (ICSM and Policlinico of Bari), imported via ETL procedures from the hospital information system (NKI), or suggested by the PDSS/VC on the basis of the guidelines implementation.

- Communication: store the interactions among components, such as messages sent by the decision support components to the GUIs.
- ServiceRequest: are used to store orders of virtual capsules.
- QuestionnaireResponse: are used to store the answers to the questionnaires that are delivered to patients through the smartphone app.

Table 2 shows counts for each category of resource and for each hospital, considering only data on the real patients enrolled in the pilot, and excluding test patients and resources related to technical information internally exchanged among the system components.

Table 2 - number of resources for each type and for each CAPABLE installation as of June 30th

Resource Type	Number of instances Italy	Number of instances NKI
Observation	3743 (1739 Pavia, 2004 Bari)	525
MedicationRequest	504 (169 Pavia, 335 Bari)	1321
Communication	16770 (9708 Pavia, 7062 Bari)	1739
ServiceRequest	13 (11 Pavia, 2 Bari)	15
QuestionnaireResponse	621 (283 ICSM, 338 Bari)	154

By comparing Table 2 to Table 1, it can be observed that a lot of Observation and Communication resources were excluded from the counts, as they are related to technical information. Such information mainly includes the results of abstractions created by KDOM, data coming from the sensors module, and technical messages among the components. As an important note, after considering the high number of Observations that are stored in the DP for technical purposes (in this case the 97.8% of the total Observations in Italy and the 94.9% in NKI), and after discovering that the majority of such data came from the sensors module (67.7%), we decided to lower the frequency of synchronisation between the sensors module and the Asus cloud, thus reducing the number of daily observations stored on the DP.

The differences in the counts for other resource types are less evident, as they are instead related to data that have been inserted for test patients to try some specific functionalities such as capsules prescriptions or response to questionnaires (consider that tests have been mainly performed at ICSM).

For Italy, out of the 3743 considered Observations, 509 are related to symptoms. Symptoms were reported by 36 out of 38 patients, and in total we have recorded 48 distinct symptoms. The symptoms were mainly inserted by patients (434 instances), but there were some cases in which it was the doctor who reported (75 instances). Oncologists have reported 8 distinct symptoms related to 6

distinct patients. In NKI, 87 observations were related to symptoms (until 30 June 2023). In total, six patients reported symptoms, and 7 distinct symptoms were recorded (arthralgia being most reported). Like in Italy, the symptoms were mostly reported by patients (83 observations), and one distinct symptom was inserted (and validated) by a physician (4 observations).

Besides symptoms, Observations are used to store clinical data, measurements such as weight and blood pressure, actions in response to recommendations (accepted/declined), and reporting of completed virtual capsules.

As regards MedicationRequests, it is possible to observe a difference between Italy and NKI, highlighting a higher number of resources in the Dutch DP. This is due to different workflows for storing treatments in the two centres. In Italy, no automatic data import from the EHR is performed, due to the unstructured nature of this type of information in the hospital information system. For this reason, all the treatment prescriptions are manually inserted by doctors in the CAPABLE dashboard. In NKI instead, an ETL procedure is run every night and it imports *all* the treatments related to patients, including past treatments also not related to cancer. This explains the observed difference. Out of the 504 MedicationRequests present on the Italian DP, 448 represent actual prescriptions, whereas 56 are medication proposals generated by the PDSS and sent to the dashboard as recommendations. As regards the status of each medication, 422 are Active, 79 stopped and 3 were cancelled. In NKI, out of the 1321 MedicationRequests stored on the DP, 1311 were referred to actual orders and 10 were medication proposals. All the MedicationRequest status was set to active.

Table 3 shows the counts for the QuestionnaireResponse resources classified by the type of questionnaire. In total there are 9 questionnaires delivered by the app. The detailed scheduling of questionnaires marked with a * is presented in D7.1 (psychological workflow).

Table 3 - Number of QuestionnaireResponse resources for each type of questionnaire available through the CAPABLE app.

Questionnaire	Frequency (minimum)	Eligible patients	Count
Italy			
Habits	Once (at enrollment)	All	40
GAD7*	Every 90 days	All	53
PHQ9*	Every 90 days	All	52
Question on death*	Every 90 days	All	57
Question on sexual life*	Every 90 days	All	49
Emotional thermometers*	Every 2 weeks	All	71
Need help thermometer*	Always available	All	192

Insomnia Severity Index	Every 30 days	Patients with sleep disorders or who report insomnia as a symptom	21
BREQ-2	At enrollment and at the end of the study	Patients who are allowed to perform a daily walk	48
NKI			
Habits	Once (at enrollment)	All	16
GAD7*	Every 90 days	All	21
PHQ9*	Every 90 days	All	17
Emotional thermometers*	Every 2 weeks	All	48
Need help thermometer*	Always available	All	56
Insomnia Severity Index	Every 30 days	Patients with sleep disorders or who report insomnia as a symptom	22

Figure 2 shows a histogram of the number of questionnaires filled in by the patients in Italy. In particular, there are 13 patients who filled in up to 11 questionnaires, 19 who filled in 12-20 questionnaires, and 6 patients who filled in more than 20 questionnaires. It is important to point out that the number of questionnaires filled in by each participant depends on the amount of time a patient has been enrolled in the study. Nevertheless, there is some data that need further investigation, as the number of observed responses is not consistent with the expected for at least 4 subjects. This data is useful to inspect the DP and to understand if the recorded information is due to an error of the system or to usability issues that cause a patient to report in the wrong way. For example, for these 4 patients it turned out that the fact that the Need Help thermometer is always available created confusion as they kept filling it in even on the same day. These patients were contacted to clarify the use of this specific questionnaire. This result was also used to improve the training procedure for newly enrolled patients.
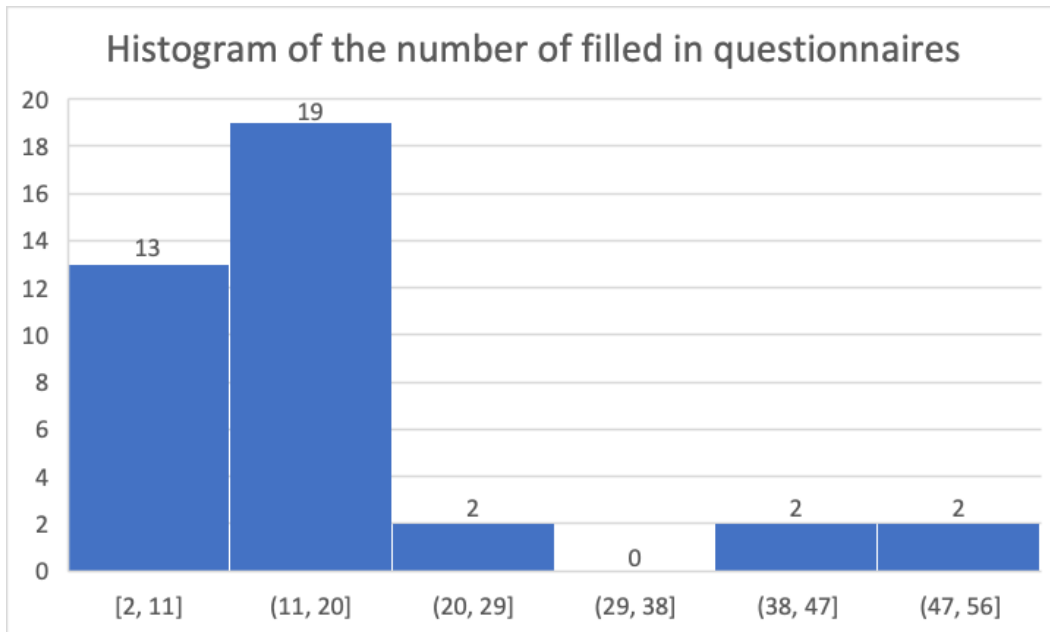
Figure 2. Histogram of the number of questionnaires filled in by each patient.

In NKI, the trend of completing questionnaires is similar. Although it is worth mentioning that 33/56 records of the Need Help button are coming from one single patient. This same patient also had 26/48 records for the Emotional Thermometers. This is a result of completing the questionnaires multiple times a day, since it would not disappear from the homepage of the CAPABLE app. For this reason, some other patients also completed a few questionnaires multiple times. The patients have been contacted by the research team for explanation when this problem was seen. Overall, apart from those exceptions, the completion of the questionnaires is in line with the proposed flowcharts.

For Communications, we performed a preliminary analysis of the messages that were sent by the DSS components (Virtual Coach and Physician DSS) to the patient app and the physician dashboard. This is possible by selecting those Communications that have "*virtual_coach*" or "*physician_dss*" as a source and belong to the categories "CAPABLE message for Patient Application" or "CAPABLE message for GUIs".
Looking at the payload of the Communications, it is then possible to further classify the messages in categories to have a detail of the information that is delivered through the message. In particular, we can distinguish between the following:
- Messages sent by the PDSS to the physician dashboard:
  - message: recommendations to the physician dashboard not involving the suggestion for a medication. In this case the payload includes the code of the guideline where the recommendation is found as the interventionCode, and a text field including the specific text of the recommendation
  - medication-proposal: recommendation involving a suggestion for a medication. In this case the payload includes the RxNorm codes of the drug(s) mentioned in the recommendation as the interventionCode, and the reference to the Goal Resource where the recommendation related to the treatment is stored.
- Messages sent by the Virtual coach to the patient app (see Table 1 in document D5.5 for the complete list and detailed description [1])

- caregiver-contact: messages that are sent in response to a symptom reported by the patient and that requires a contact to the healthcare team
- form-fill-in: requests to fill in a given form, which usually refers to a questionnaire
- management-tip: messages that are sent in response to a symptom reported by the patient and are related to the symptom management
- medication-update: messages used to inform the patient when a new drug is prescribed by the physician or when an existing treatment is modified
- motivational-tip: messages periodically sent to the patients to motivate them in performing wellbeing interventions
- prevention-tip: prevention messages sent to patients in presence of any condition that could trigger one of the adverse events managed by the guidelines implemented in the CAPABLE system
- symptom-report: messages to require the update of a previously reported symptom
- visit-reminder: messages to remind a visit at the hospital
- experience-sharing: messages sent when a patient reports the end of a symptom and that suggests to share their experience on the AIMAC forum
- hobby-reminder: messages periodically sent to patients to ask them if they are still performing one of the activities that are declared as preferred activities during enrollment

- Messages sent by the Virtual Coach to the physician dashboard: used to alert the doctor if the patient is not regularly synchronising the smartwatch and to notify when blood pressure is reported by the patient.

As reported in Table 2, up to June 30th we recorded 16770 Communications of this type in Italy and 1739 in NKI. The differences in the activity of the Italian decision support components with respect to the Dutch system is currently under investigation to exclude any malfunctioning on either site.

For Italy, we have performed a detailed analysis of the messages in the communications on the basis of the above listed categories as of June 30th 2023. This analysis is presented in Table 4. This interim analysis was not performed in NKI due to constraints on the data processing before the end of the pilot study. We will report the final analysis in deliverable D7.9 due on M48.

Table 4 - Detail on the communications stored on the DP (as of June 30th 2023, for patients enrolled in the study).

Table 4 shows

Communication type	Italy	NKI
From PDSS to physician dashboard		
Total	9921	450
Message	9870	Will be reported in D7.9 (M48)
Medication proposal	51	Will be reported in D7.9 (M48)
From Virtual Coach to patient app		
Total	6889	1289
caregiver-contact	81	Will be reported in D7.9 (M48)
form-fill-in	2370	Will be reported in D7.9 (M48)
management-tip	924	Will be reported in D7.9 (M48)
medication-update	412	Will be reported in D7.9 (M48)
motivational-tip	467	Will be reported in D7.9 (M48)
prevention-tip	313	Will be reported in D7.9 (M48)
symptom-report	1943	Will be reported in D7.9 (M48)
experience-sharing	54	Will be reported in D7.9 (M48)
hobby-reminder	82	Will be reported in D7.9 (M48)
From Virtual Coach to physician dashboard		
Total	160	Will be reported in D7.9 (M48)

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consistent activity of the PDSS on the Italian DP, and this was partially due to a bug in the component that was sending recommendations multiple times. More details on this bug can be found in Section 5.

Besides the messages sent to the GUIs detailed in Table 4, the DP also stores Communications that represent technical communications among the components. These include communications that have KDOM and GOCOM as sources. In Italy, there are 52742 communications sent by the KDOM to the PDSS (in response to requests to compute abstractions) and 57 communications sent from GoCom to PDSS, all referring to medication proposals on Goals. In NKI, there are 3300 communications sent by the KDOM to the PDSS (in response to requests to compute abstractions) and no communications sent from GoCom to PDSS.

Wellbeing interventions, i.e. virtual capsules, are managed in the system by two types of resources:

ServiceRequest and Observation. ServiceRequest is used to store those capsules that are *prescribed* or *contraindicated* to patients. Prescribed capsules are meant to be executed with a specific schedule and are consequently monitored by the Virtual Coach, contraindicated capsules must not be executed by the patients and are consequently not made available on the app. Observation resources are used to store the execution of a specific activity when reported by the patient.

In Italy, we have a total of 13 ServiceRequest resources saved on the DP as of June 30th, with the following characteristics:
- they refer to 9 distinct patients
- 10 are related to prescribed activities and 3 are related to contraindicated activities (these all refer to the same patient)
- prescriptions refer mostly to walking activity (9 instances related to 8 patients). One instance is related to the Garden Bowl capsule
- contraindications are related to breathing exercises, tai chi and yoga.

In NKI, all capsules are set in the default setting as "up to patient". The Garden Bowl capsule is always set to contraindicated as requested by the medical ethical board (these correspond to the 15 stored ServiceRequests). Additional contraindications have not been set up to date. Prescriptions also have not been made. Reasons for this is that the patients exceeding the thresholds on insomnia/anxiety have been referred to additional care and follow mindfulness based interventions elsewhere.

Table 5 shows the summary of the resource related to the reporting of capsules in Italy and NKI.

Table 5 - Virtual capsules reporting activity (until June 30th 2023)

Virtual Capsule	Italy	NKI
My usual walk	138 (8 patients)	15 (4 patients)
Garden bowl	23 (3 patients)	N/A
Breathing exercises	18 (7 patients)	1 (1 patient)
Imagery training	8 (6 patients)	2 (2 patients)
Vase of gratitude	7 (3 patients)	0
Photo voice	11 (3 patients)	0
Physical activity promotion	12 (3 patients)	2 (1 patient)
Tai Chi	2 (1 patient)	0
Yoga	1 (1 patient)	3 (1 patient)
Total	220 (15 patients)	23 (5 patients)

From these data it is possible to notice that the prescription of wellbeing interventions is not frequent in any of the centres, and, even when present, mainly regards the walking activity. In general, the

decision of performing such interventions is up to the patient. From the data in Table 4 it results that, in Italy, 40% of the patients reported at least one activity. In NKI, this is only 31%. From the Italian reports, it is possible to see that there are patients who are regularly reporting their walking activity, and also the garden bowl is regularly performed by the subjects who select this activity. The number of reports varies among activities because of the frequency expected for each activity (for example walking is expected three times a week, while for the garden bowl once a week is enough). Patients have also tried other activities such as imagery training and breathing exercises, but these are not reported regularly.

Both for prescriptions and reports, we expected a higher number of entries in the DP. For reports, we cannot exclude that patients find difficulties in reporting the completed activities through the app. This will be clarified with the analysis of the final usability questionnaires performed at the end of the study. In any case, these preliminary observations highlighted criticalities in the usage of this functionality. One of the possible reasons for this is that at enrollment patients receive a lot of information and are more focused on understanding the technical aspects of the system and its general functionalities, and do not perceive the value of these non-pharmacological interventions. To try to overcome such a burden, the CAPABLE team has slightly revised the enrollment procedure, by reserving a dedicated session with the psychologist to explain in detail the functionality of the capsules and to educate the patient on the importance and possible benefits of these interventions. In addition, an integrative educational material has been prepared and it is delivered to the patients after this dedicated session. An example of the Italian version of this material is given in Figure 3.

Figure 3. The additional educational sheet purposely created to better explain the virtual capsules (Italian version). This is now provided to every new patient or patients coming to control visits

3.3 Smartwatch usage

At enrollment, patients are instructed to wear the smartwatch as much as possible, to have a complete tracking of the data related to lifestyle habits. During the pilot study, the usage of the smartwatch is monitored in two ways: (i) via direct interaction between the patients and the technical contact points and (ii) by an automatic monitoring strategy that will be described in Section 4.2. The monitoring activities are aimed at detecting potential issues both at the technical level (e.g., lack of data synchronisation with the Asus cloud) and at the patient level (e.g., lack of use). It is important to timely detect these issues to ensure the quality of the collected data.

In Italy, we identified three types of behaviour: (I) patients who constantly wear the smartwatch with only small gaps in the usage, (II) patients who use the device not constantly, alternating periods of usage and periods of lack of usage, and (III) patients who, after a while, discontinued the use of the smartwatch. Reports dated June 30 and related to the previous two weeks highlight 13 patients in group I, 8 patients in group II, and 6 patients in group III, for a total of 32 patients. For the remaining 6 patients, 2 had dropped out of the study, 3 had technical problems with the smartwatch during those two weeks, and 4 were enrolled but still had to have their device setup due to delay in device delivery by the vendor.

By directly interacting with patients, the Italian contact points detected a major issue related to difficulties in charging the battery of the Asus smartwatches. Patients reported the sudden impossibility of recharging the watch and even the indication to keep the connectors clean didn't solve the problem. The smartwatches affected by this problem were first returned to the contact points who tested the devices to exclude possible mistakes made by the patients. After verifying the presence of a technical issue, the contact points contacted the suppliers to return the faulty devices and to ask replacement. During the first study period, in Italy we had to return 9 smartwatches (25.7%) for problems related to battery charging. This process took on average 4 weeks. Since the percentage of faulty smartwatches is considerably high and the time spent for replacement has an impact on the data collected by the smartwatch, UNIPV as the project coordinator is in the process of verifying directly with the Asus company the causes of the issue and of requesting a set of spare smartwatches to be able to immediately replace the faulty devices without having to wait for the return process to complete.

In NKI, we identified the same types of behaviour in patients. Most patients are still wearing the smartwatch whenever possible. However, patients do not always wear the watches during the night, which is caused by the size of the watch. From the 16 patients, 4 have returned or replaced the watch due to charging issues (25%, thus a percentage very similar to Italy). In NKI, replacement of the watches is not available, as we have to send them in for repairs (and therefore taking longer). Three patients reported skin rash due to the smartwatch, of which 1 patient has returned the watch to stop wearing it completely (almost causing a drop-out in the study). The other 2 patients stopped wearing the watch during the night or during hot weather outside. Around 50% of patients have been in contact with the study team about the long taking updates in the Omnicare Hub app (slowing the smartwatch) and in the majority of patients there is no display of smartwatch data in the CAPABLE app.

4 Monitoring the CAPABLE system performance

4.1 Monitoring the CAPABLE Components Status

The CAPABLE System is inherently a distributed one since it relies on several independent components reading information chunks available on the DP and incrementally adding new ones. CAPABLE is not strictly speaking a real time system. However, to ensure a prompt processing of the information available on the DP it is mandatory that all the components always stay operational. Failure of any component may delay or even prevent the writing of an intermediate piece of information on the DP, eventually stopping the chain of contributions and spoiling the reasoning process.

To address this issue, from the very beginning we devised a way to check the components operational status. By design, all the components interact with the CM that is responsible for coordinating their joint reasoning efforts. The interaction of any component with CM leverages the *long polling technique* so that they regularly check in with the CM about the occurrence of any event of interest that may trigger their interventions. Since the CM keeps an extensive set of logs, their analysis through an independent tool seemed the most appropriate way to check for the component responsiveness. Moreover, this also protects against the failure of the CM itself that in that case would stop sending logs altogether. A log analyzer has been built for extracting the information concerning the component interaction and reporting about it. Those reports are then shared among the developers several times per day, augmented with specific warnings whenever a failure of responsiveness of a component is detected.

Sharing those reports among the developers has been achieved in two different ways. At ICSM, the architecture of the system allows connecting to the Telegram Service APIs which is very handy for broadcasting short messages to a group of selected people, making them available in a comprehensive way. We therefore created a restricted group on Telegram, that is only accessible through invitation by the owner (UNIPV), where service messages are regularly pushed and received by the developers on their smartphones. The same group is also used to exchange messages about upkeeps or external activities, such as foreseeing / confirming the proper enrollment of new patients. As an example, Figure 4 shows the screenshot of that group reporting on the status of ICSM and Test Virtual Machines. It also says that additional reports have been generated concerning the patients' arterial blood pressure acquired by the smartwatches. Those additional reports help in independently monitoring the use of the smartwatches.

The Telegram Group turned out to be very effective for sharing log messages, since it collects and makes them available at a single dedicated access point. While this worked for ICSM, the ICT staff at NKI did not give us the required permissions to access the Telegram Service APIs for posting the log messages due to their policies. Thus in this case we had to resort to plain email which is the only channel they allowed us to use. As an example in Figure 5 we show the reports from NKI including the very same contents available on Telegram but provided through email.

In any case developers are always aware of the current state of the components. The report includes

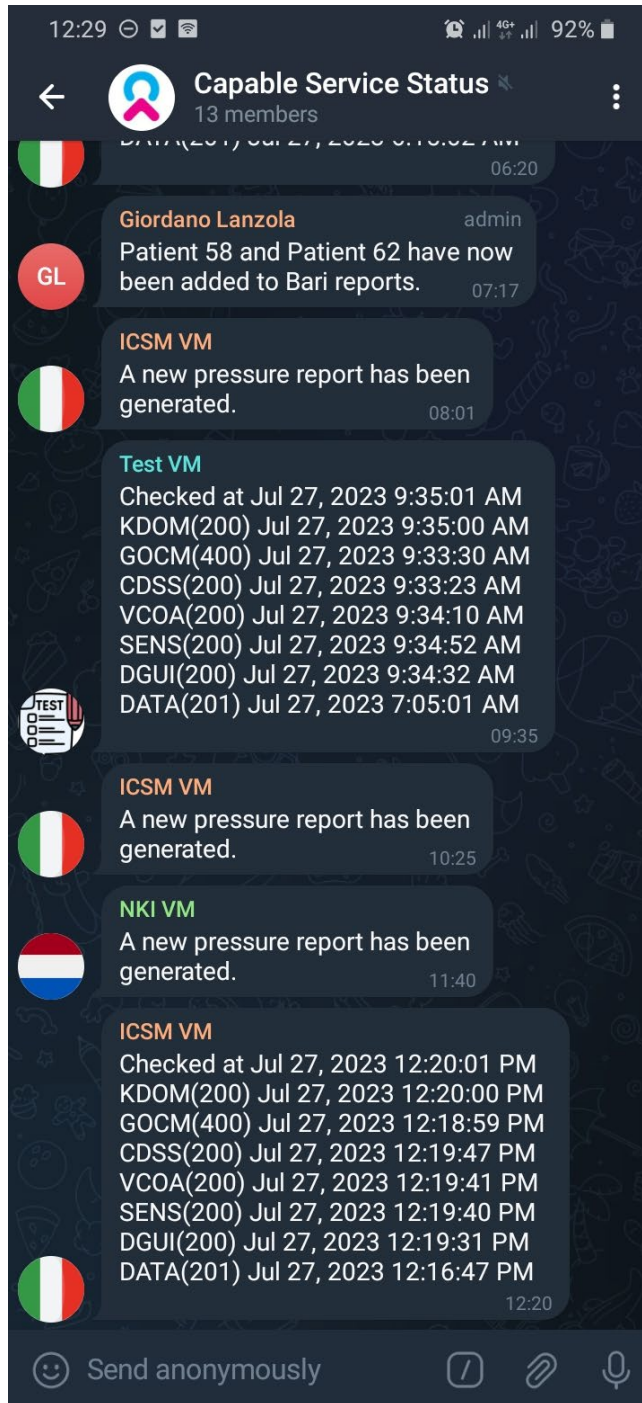special warnings in case of lack of responsiveness.

Figure 4. The Telegram window shown on a smartphone where messages concerning the operational status for the CAPABLE components deployed at ICSM and at the Test VM are posted.

Figure 5. The messages concerning the CAPABLE component status at NKI are delivered through email.

Virtual Coach also implements a similar solution. Specifically, it has a script that periodically checks the VC log for error entries and sends notifications via Telegram. In this way, VC is able to discover situations when it correctly interacts with CM, but there are issues with other components or VC itself. For example, in late June the Deontics Engine at ICSM became unresponsive for some time and VC was not able to run CIGs. Thanks to the monitoring system, VC was notified about this situation and we were able to handle it accordingly.

4.2 Daily reports on smartwatch data

As mentioned, another way to monitor the CAPABLE system usage concerns the patients' use of the smartwatches. Some issues we found in this area are: technical usability on the patients' side; early battery wear out; patients forgetting to don the device; calibration problems; etc.. All of those issues resulted in the acquisition of poor or unreliable data if not in the lack of any acquired data altogether. Moreover, CAPABLE only uses those data in an aggregated form, such as for monitoring over time the physical activity accomplished by patients to possibly suggest walks. Thus, the availability of those data is sparse over time and any issue with their acquisition could take too long to be detected just relying on the CAPABLE data.

The smartwatches are provided by ASUS so that each patient sends their personal data to the ASUS cloud, where the CAPABLE system regularly connects to download data for all patients. Since data is always sent to the ASUS cloud before entering the CAPABLE system, we chose to directly query the ASUS site as a means of monitoring the smartwatches. Being independent from CAPABLE, this choice also provided us with an additional redundancy. Finally, we chose to monitor the patients' arterial blood pressure, which is one of the most frequent data collected by the smartwatch, also

requiring the accomplishment of regular calibrations on the patient's side.

We implemented an automatic robot that twice per day downloads arterial blood pressure data for all the patients. To avoid overloading the cloud we split the download in 3 separate tasks, one for each patient group since each of the three groups (ICSM Pavia, Policlinico di Bari, NKI) has a similar number of cases. For the current report, only the Italian sites were considered, for the data processing constraints mentioned in previous sections. The data downloaded are used to generate plot charts (one for each patient) and organised into a printable booklet in PDF format that may be accessed or printed by any interested person with the right credentials. As a trade off between performance and readability of the charts we chose to download each time the arterial blood pressure data related to the past two weeks. In Figure 6 we show the entry page of the site where the blood pressure data are available. Data is grouped by the centres (up to now ICSM Pavia and Policlinico di Bari). A last group is used to merge all the Italian patients. Figure 7 shows a blood pressure chart for a single patient. The technical contact point at the hospital periodically opens the reports to check if the patients are regularly using their smartwatches, and takes action if any critical behaviour is spotted.

Thanks to those reports we were able to spot some inconsistencies on the ASUS cloud server, mostly concerning timeout in responses and erratic behaviour in sending us the data requested. Those issues have been promptly signalled to the maintainer and while waiting for their intervention we enforced additional controls and integrity checks to make sure that the data sent were consistent.
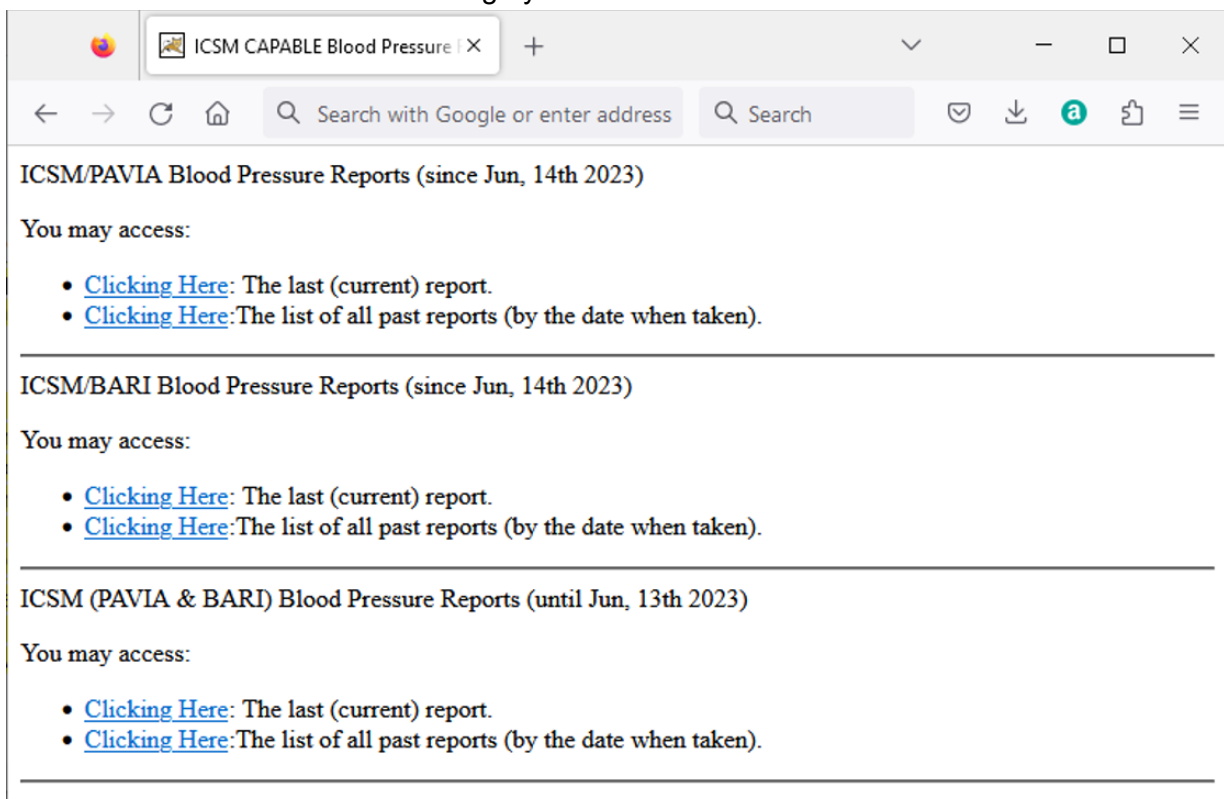

Figure 6. The comprehensive view of the site where both the last pressure report (i.e. current) and the previously extracted ones are archived.
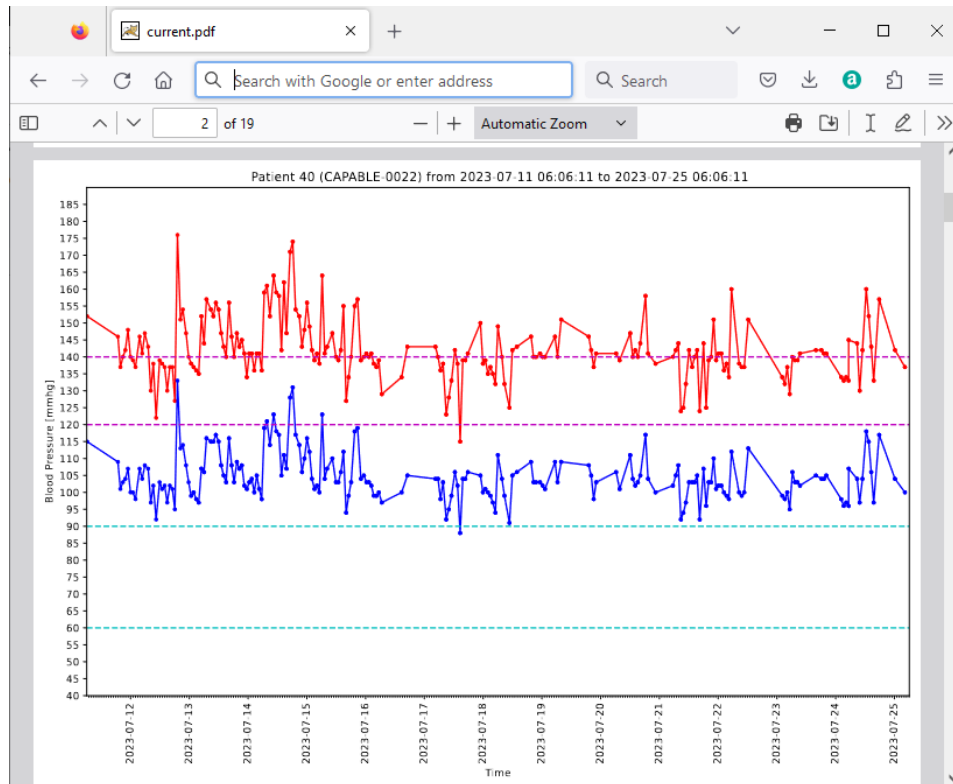
Figure 7. Sample of an arterial blood pressure chart concerning a patient taken over a 2 weeks period. This report does not show any missing data.

4.3 Bug tracking and management

According to the issues management plan described in deliverable D7.6 [2], the technical contact points at the hospitals together with the developers of the CAPABLE system components have set up a bug tracking file with the goal of describing and managing any issue that might arise during the use of the system.

The file has been first used during the pre-pilot testing phase carried out by healthy volunteers selected among researchers of the CAPABLE teams at UNIPV, ICSM, NKI and UPM. These volunteers simulated the behaviour of real patients and doctors by using the system as it would be used in reality. The two applications (patient app and physician dashboard) were used as the main interfaces with the system. Pre-pilot tests were run on the pilot-ready version of the system. Initially tests were performed on the test environments (TEST VM and Continuous integration VM), and were then extended to the environments set up at the hospitals as soon as these became available. During the pilot study, we decided to keep the test environments active and also to have some test accounts within the hospitals' environments, to be able to reproduce possible issues found by real patients.

The pre-pilot testing phase allowed consolidating the bug reporting and management process, together with the structure of the reporting file.

The file is a spreadsheet including the following fields:
- Tester: identifier of the tester - can be both a person of the technical staff or a real patient

- Id: id of the tester/patient on the CAPABLE DP
- Environment: VM where the issue was detected (it can be TEST VM, Continuous Integration VM, CAPABLE deploy at ICSM, CAPABLE deploy at NKI)
- GUI: application that allowed detecting the issue (patient app or physician dashboard)
- Description: detailed description of the issue
- Type of issue: classification of the issue within a set of categories (bug, missing functionality, translation)
- Other testers that experienced the same issue: used to avoid reporting the issue multiple times
- Responsible partner: developer(s) who could explain or solve the issue
- Status: issue status, including possible comments/discussion. When the status is Solved the issue is removed from the file, and moved to another file that lists the solved issues.
- Screenshot: screenshots or videos of the GUI where the issue occurred to integrate the provided textual description
- Notes: possible notes by testers or developers

All developers monitor the status of the file. As soon as a new issue is reported, the partner(s) responsible for it are in charge of reproducing it and dealing with it. Since solving an issue might not be immediate and might require the collaboration of more than one partner, the interaction can be done using the file itself (Status column), during separate meetings among developers, or during TF1 meetings that are held weekly (TF1 is the developers' task force). During these meetings a summary of the main pending issues is presented and possible solutions are discussed. Once the issue is solved, it is first deployed and tested on the test environment. Then, if the changes require the deployment of a new version of one or more components, the technical contact points identify the best moment to perform such intervention, according to the scheduled enrollments and other activities that might be affected by the system updates. Patients are notified of possible unavailabilities of the app in the time slot selected for the update procedures. This is done via the Mobile Device Management (MDM) system, and a message is broadcasted to all the patients and is visualised on the smartphones.

In the following section we will present a report on the main issues that have been found up to June 30th 2023 and of the main technical improvements that were proposed to deal with them

5 Preliminary report on issues management

In this section we provide a summary of the issues identified on the CAPABLE system. We will separate the issues found during the pre-pilot and the issues that were raised after the first patient was enrolled in the system.

During pre-pilot, 112 issues were identified in the system, whereas 57 issues were identified after the start of the pilot study. These issues were reported by the patients and reproduced and verified by the technical contact points before being added to the reporting file. Table 6 and Table 7 show a summary of these issues. In particular, we report the number of issues found during the pre-pilot and the pilot (until June 30th) phases and a brief description of the main ones. We have divided the issues identified using the patient app from the ones found using the physician dashboard. For each GUI, we further classify each issue on the basis of the high-level functionality it is related to. Such functionalities have been identified as the main menu items in the two applications. In addition, for

the patient app we highlighted a set of issues that are related to the use of the Asus smartwatch and several issues related to localisation or wrong phrasing of messages or recommendations (only the patient app is localised, so these issues are not present in the physician dashboard).

Table 6 - summary of the main issues detected from the patient app

PATIENT APP	Pre-pilot		Pilot	
Functionality	*Number of issues*	*Brief description of the main issues*	*Number of issues*	*Brief description of the main issues*
Login/Authentication	4	Missing password security level criteria	1	Wrong alert of incorrect user name
Home	23	Problems with performed activities in the calendar view Problem with treatments (wrong dates) Treatments at the hospital visualised in the patient app	5	Weight update Problem related to filling in questionnaires from the Home page (only one patient)
Inbox	11	Missing contact level Wrong frequency for symptom update request Issues with time zones in the messages	19	Wrong timing of reminders for follow-up (3 months) questionnaires Empty Inbox Multiple notifications for questionnaires in the inbox if the patient hasn't filled-in
Symptoms reporting	10	Reporting the end of a symptom Symptoms disappearing after reporting (server update problem)	8	Reporting the end of a symptom Symptoms disappearing after reporting (server update problem)
Virtual Capsules	7	Reporting a completed virtual capsule Missing content in virtual capsule Display content of virtual capsules	1	Wrong walking activity report (only one patient)
Education	1	Missing quizzes in educational material	0	

Translation Issue or wrong phrasing	18	Wrong translations Sentences still in English Wrong phrasing of sentences	3	Wrong translations Sentences still in English Wrong phrasing of sentences
Asus data synchronization	5	Problems in connecting to the Asus cloud Synchronization problems in the app	4	Problems in connecting to the Asus cloud Synchronization problems in the app

Table 7 - summary of the main issues detected from the physician dashboard

PHYSICIAN DASHBOARD	Pre-pilot		Pilot	
Functionality	Number of issues	Brief description of the main issues	Number of issues	Brief description of the main issues
Enrollment/visit scheduling	3	Missing cancer time Impossibility to modify sleep issues field Possibility to schedule a visit in the past	3	Human errors during enrollment procedure
Homepage	4	Missing/not clear content in patients list New data notified with a delay	1	Issues on updating the patient's status
Symptoms	11	Problems on graphical symptoms visualization Problems in the symptoms list visualization (symptoms not finished, wrong source for reporting) Issues when loading the symptoms list page (very slow) Missing items in the CTCAE list	3	Issues when loading the symptoms list page (very slow) Problems in the symptoms list visualization (duplicated or missing symptom)
Treatment prescription	4	Missing measurement units Missing end-date when stopping a treatment	3	Missing/wrong codes for drugs
Achievements	3	Missing information on	1	Not clear visualisation of

(virtual capsules)		the performed virtual capsules		activities performed in the past
Recommendation	8	Missing expected recommendation Duplicated recommendations Impossibility to perform action on recommendation (accept/decline)	5	Duplicated recommendations Missing expected recommendation

From Tables 6 and 7 it is possible to notice that, in general, the number of issues decreased when switching from the pre-pilot to the pilot phase. As expected, during pre-pilot we were able to identify issues due to the systematic use of the applications, such as some wrong or missing translations, missing contents both in the virtual capsules and in response to some of the reported symptoms, and wrong visualisation of the information in the home page and calendar view of the app and in the symptoms page of the dashboard. In previous tests the functionalities were checked to verify their correct behaviour, but not yet exhaustively. As regards the pilot phase, we experienced a major bug in the patient app, related to the fact that the Inbox section was not properly updated for several patients due to a problem of synchronisation between the GUI and the DP. Even if this bug is hard to be detected, thanks to the regular contacts between the patients and the technical contact points at the hospitals, it was possible to promptly identify the issue, inform the users about the malfunctioning, and timely fix the problem. Unfortunately, when fixing the bug, all the notifications that were not correctly synchronised were sent all together to the patients, causing some further misunderstanding, such as multiple answers to questionnaires. This problem was also quickly fixed by communicating with the patients and explaining how to behave, and consequently limit the number of "old" messages to be sent in cases like this to the past three days.

In the physician dashboard, we encountered a problem related to a bug in the PDSS, which was sending recommendations multiple times, visualised on the home page even after the doctor accepted the suggestion. This also explains the high number of Communications stored in the DP by the PDSS and shown in Table 4. This bug has for sure an impact on the user experience, even though the recommendations that were sent were correct. The high number of duplicated recommendations might cause the doctor to lose focus on new recommendations. There were also few cases where a recommendation that was expected was not actually shown on the dashboard. In only one case this error was due to a problem in the guideline implementation, while in the other cases the problems were due to the synchronisation of the GUI with the DP, where the recommendations were correctly stored by the PDSS.

Another problem that was raised during the enrollment procedure is related to the possibility of human error in filling out the required field in the dashboard (e.g., the email of the patient). Since the dashboard was designed without the possibility of modifying such fields, in case of human error it is always necessary to contact the partners responsible for the development of the GUI and ask to proceed with a manual update of the wrong information, to be able to proceed with enrollment.

As mentioned in Section 4.3, the procedure for issues management that was setup in CAPABLE requires that, if an issue requires the deployment of a new version of one or more components, the

technical contact points selects an appropriate time slot and the users are advised on maintenance via the MDM. From the experience we had, the updates of back-end systems components as DP, CM, KDOM, VC, GoCom and PDSS have always been fast and no impact was reported by the patients on system use. On the other hand, updates of the back-end component of the GUIs have an impact on the compatibility of older versions of the smartphone apps with newer versions of the server. During the pilot only one impacting server update was performed by Bitsens, but this required 18 patients in Italy (those who were enrolled with previous versions of the patient app) to be contacted by the technical contact points to schedule an appointment to receive support to install the new version of the app. Most of the patients were managed remotely thanks to the MDM system and the app was updated by the technical contact point using the screen sharing functionality.

To manage the issues described in Tables 6 and 7, the components underwent some updates and technical improvements, which have required new deployments. These are briefly summarised in the following.

Case Manager (CM): CM has been the first component of the CAPABLE ecosystem to reach maturity level. This is due to the key role played by it, that sees the CM as a scheduler coordinating the tasks accomplished by all the other components. For that reason it underwent extensive testing before entering production, during which any possible criticality and improvement requested by the developers of the other components had been already addressed. Thus no changes were required to the CM codebase in production. After the initial deployment a single upkeep operation was required on both clinics to configure extended logging fitting the partition space provided by the ICT staff that created the VMs. This was also helpful in making available the monitoring facilities discussed in Section 4.1.

Data Platform (DP): Data Platform underwent few updates since the beginning of the studies in the two sites. In particular, the Communication and MedicationAdministration FHIR resources underwent some modifications and bug fixing in their attributes, and the update time window was modified for the Patient resource. Patient's details were removed from resources linked to the Patient so that personal data are never exchanged in communications between components other than the GUIs. Finally, to support the workload generated during production, the paging strategy when fetching thousands of resources has been optimised.

Extraction Transformation Loading (ETL) process: ETL is the data import process that runs every night to transfer data about CAPABLE patients stored in the hospitals' data warehouse into CAPABLE (after transforming them into FHIR resources). As mentioned, ETL is installed only in NKI. As of June 30th 2023, 100% of the enrolled patients have received at least one FHIR Resource from ETL, and 3087 FHIR resources have been imported (MedicationRequest: 2175, Appointment: 382, MedicationAdministration: 284, Observation: 246).

KDOM: the KDOM runtime environment was updated to support new temporal abstractions indicating the persistence of the following symptoms for more than two weeks: Hand Foot Syndrome, Onychomadesis, Paronychia. The KDOM design time environment was updated to support testing abstractions at ICSM and NKI sites, and an option was added to delete events queue to prevent KDOM overflow.

GoCom and PDSS: in February 2023 the Computer-Interpretable Guidelines were uploaded to the

servers (ICSM and NKI) and updated with attention to various aspects, including the resolution of code discrepancies existing between the guidelines and the corresponding physician dashboard. Additionally, recommendations were rephrased and remodelled in order to provide decision support that is more effectively aligned with the operational dynamics of the users and system in use.

Virtual Coach (VC): the VC component underwent seven updates aimed at
- Adding NL and IT translations of selected messages not handled by the patient app, motivational tips, and blood pressure check reminders (only IT)
- Adding support for disabling checking sensor data to avoid multiple warnings caused by reliability issues of the OmniCare platform and for the sensor data check workflow
- Improving handling of faulty CM rules (automatic deletion and re-creation)
- Expanding handling of ServiceRequest resources representing capsules (creation of in-memory resources capturing up-to-patient choices)
- Adding support for blood pressure check workflow (reminders for patients, notifications for clinicians)
- Extending the psychological workflow for NKI (extra message associated with the death question in the PHQ9 questionnaire)
- Adding support for patient-friendly medication name (retrieval from MedicationRequest and inclusion in messages sent to the Patient App)
- Adding support for delaying internal VC reminders when the patient is hospitalized
- Adding response-to-score mapping for the BREQ2 questionnaire to properly handle localized responses

Sensor module: this component was updated with the following technical improvements:
- Added mechanism for automatically reassigning existing smartwatch to a different patient and for automatically reassigning new smartwatch for the same patient in case of battery issues
- Added support for alternative Omnicare endpoint to cope with the reliability issues of the OmniCare platform
- Added calculating most active period during a day and improved total sleep time calculation
- Changed observation generation frequency for saving data to DP

Doctor Dashboard: before starting the enrollment of the patients in the pilot study the doctor dashboard underwent significant updates to comply with the requests that derived from the results of the penetration tests that were performed in NKI from December 2022 to January 2023. After the beginning of the study, further technical improvements were needed. These were aimed at:
- Localising inbox push notifications
- Implementing questionnaire name translation
- Making the visit note as an optional field
- Adding patient status change to activity timeline
- Saving medication display name to DP resource
- Fixing scheduler and calendar
- Customising the need help logic for daily plan
- Allowing doctors to close symptoms from dashboard with end date
- Fixing the symptoms ordering

- Showing ongoing symptoms from previous months
- Include medications coded as RxNorm extensions
- Fixing pagination
- Skipping medications with no timing bounds start for mobile app
- Adding missing inbox tag, and fallback

Patient Mobile Application: the following technical improvements were performed in the patient app:
- Inbox push notification localization and wrong/missing translations
- Symptom reports syncing
- Refresh token and logout fixes
- bug fixing in the capsules functionality (photo voice crash and missing references)

6 Conclusions

In this report we have presented an interim analysis of the usage of the CAPABLE system and of the technical improvements that were performed to manage the issues that were raised during the first months of the pilot. We have also described the solutions that were set up to monitor the system status and performance. The presented analyses are performed on the data extracted from the system and from the monitoring process up to June 30th 2023.

From the results of the analysis we can draw some useful conclusions for the following of the study. First of all, running an intensive pre-pilot testing phase in the two production sites was extremely useful to detect several issues that could be fixed before starting the real clinical study. In addition, the monitoring process that was setup to check the status of the system and of its components was effective for the timely detection of issues that might have an impact on the users. Such issues have been managed by effective communication among developers and contact points at the two sites. The preliminary analysis of the data stored in the DP was useful to detect some problems such as the under-use of the capsules functionality or the repeated use of some questionnaires. These issues need to be monitored further to understand if they can be related to usability problems in the application. From the technical perspective, the huge amount of Observations stored in the DP allowed us to redefine the frequency of synchronisation of the Sensors Module with the Asus cloud, to avoid overloading the system. Thanks to the smartwatch activity monitoring it was possible to detect both episodes of under use by the patients and failures in the sensors data retrieval flows due to the temporary unavailability of the Asus APIs. The Mobile Device Management system was very useful for remotely interacting with patients and to avoid unnecessary visits to the hospital related to (even trivial) technical problems or requests for support. Since the MDM system is available for patients using the smartphone provided by the project, the choice of providing a dedicated smartphone to the majority of the patients was appropriate.

Some open issues remain unsolved, both related to the CAPABLE system and to the Asus smartwatches. As for the smartwatches, the main problem is related to battery recharging, which were experienced by a considerable number of patients both in Italy and in NKI. This is independent from the project (the smartwatch is a commercial product), but we are trying to set up a procedure to allow an immediate replacement of the device avoiding waiting time (and data loss) for the patients. As regards the CAPABLE system, we will monitor the issues in the remaining months of the pilot study and we will update the report on 48 (D7.9).

7 References

1. Deliverable D5.5: https://zenodo.org/record/7096208
2. Deliverable D7.6: https://zenodo.org/record/7603369