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Customisation guidance document for CAREGIVERSPROMMD platform Screening and Interventions services

CAREGIVERSPRO-MMD PROJECT

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Executive summary

The document shows that the data generated by C-MMD Platform will be processed and collected within a Summary Report (hereinafter SR) which is expected to have clinical and social meanings and to be able to support specialists in providing more and more customized and tailored clinical and social interventions to persons living with dementia and their main.

The objective of the C-MMD platform is primarily intended to detect changes in the clinical and social status of the dyads. These changes may be notified to the health and social professionals through a report, as well as to caregiver. This report should improve diagnostics and therapeutic processes as well as the most important driver for financial savings.

The SR aims to provide information about the health and social conditions of PLWD and their caregivers, with the purpose of integratinge their general health picture with a tailored and specific insights on MMD and MCI, according to thethis is in line with the European Union' recommendations in terms of interoperability with other systems and meaningfulness offor the research forof the innovation in the medical Health records.

The **lack of interoperability** is**,** as stated by the European Commission itself, a delicate and problematic issue for the use of electronic health record systems. Fully interoperable electronic health record systems should ease the access to users' information, enhancing the quality and safety of user care and ensuring the accuracy and the safety of the user data. According to services currently implemented into the platform and tested for usability evaluation, the C-MMD platform, while enabling to monitor the activities of its users and record their behaviours, as well as psychological and health conditions, it also provides more than just a static repository for specific data, but a combination of information, knowledge and feedback, in order to facilitate the integration with the EHR system.

There are semantic and technical issues in order to transform the SR into digital data which shall be meaningful and interoperable; but given the requests of information expected by social and health professionals, the SR generated by this huge amount of data can represent a way to overlap the lack of interoperability and provide added values toward the analysis and treatment of dementia across Europe. The research sphere, therefore, can benefit of the study described in the document. There is no lack of data for dementia research, but the need to better exploit more these data: the possibility to produce sharable data produced by a continuous monitoring may significantly improve the research in the field, and the data y can be exploited in different ways. To fully capture its potential, C-MMD SR may be considered as a tool to produce routinely big data which allow a better understanding of the behaviours and environments of dementia people living with dementia, not only after diagnosis, but for prevention, early identification and diagnosis, or even to retrospectively analyse the years leading up to diagnosis.

List of Acronyms

Acronym	Title
API	Application Programming Interface
CALLIOPE	CALL for InterOPErability
C-MMD SR	C-MMD Summary Report
CRS	Clinical Reporting Service
EHR	Electronic Health Records
eHGI	eHealth Governance Initiative
EMR	Electronic Medical Records
epSOS	European Patients' Smart Open Services
FHIR	Fast Healthcare Interoperability Resources
GDS	Geriatric Depression Scale
HL7	Health Level Seven International
MCI	Mild Cognitive Impairment
MMD	Mild to Moderate Dementia
MR	Medical Record
MRS	Medical Reporting Service
NHS	National Health Service
PHR	Personal Health Record
PLWD	Person Living with Dementia
PS	Patient Summary
SR	Summary Report
SRS	Social Reporting Service

List of Tables

Table 1. Sources of data and information to be included in the C-MMD Summary Report 13
Table 2. Data from the non-pharmaceutical interventions to be reported in the Summary Report 16
Table 3. Functional and Non-Functional requirements of C-MMD SR 23
Table 4. Dimension for evaluation of the C-MMD SR 25

List of Figures

Figure 1. Dataflow to create the Summary Report 17
Figure 2. Design example of the content adaptation (user selection) 28
Figure 3. Design example of a new sensitive data access request 28
Figure 4. Design example of structure adaptation 29
Figure 5. Design example of structure adaptation 29
Figure 6. Screenshot from a demo medical reporting template 33
Figure 7. Screenshot from a demo social reporting template 34
Figure 8. Screenshot from a demo social reporting template 35
Figure 9. Mind-map of the data model behind the short social reporting service 36
Figure 10. Example of risk detection using out-of-range data plot over historical data in the social, medical and/or personal reporting 37

Table of contents

1 Introduction 8
2 State of the art: toward the integration to EHR standards 9
2.1 Models of records 9
2.2 EU forewords 10
2.3 Requirements for interoperability 11
3 C-MMD process for the creation of a “Summary Report” 12
3.1 Data sources 12
3.1.1 User’s profile 13
3.1.2 Screening 14
3.1.5 Treatment Pharmacological Adherence 18
3.2 Expected results: Interviews with health and social professionals 18
4 C-MMD User Summary Report 22
4.1 Structure 22
4.2 Functional and Non-functional requirements 23
4.3 User Consent and Access 24
4.4 Contents 25
4.5 Evaluation 25
5 Technical Requirements: The Clinical and Social reporting service 27
5.1 The Clinical Reporting Services of C-MMD SR 30
Functionality descriptions 32
Description of the Available Data 32
Value Dependencies and Types of Graphs 32
Medical Reporting 33
5.2 The Social Reporting Services of C-MMD SR 34
5.3 The Personal Reporting Service 36
6 Recommendations and considerations 39

1 Introduction

This current deliverable aims to provide recommendations and guidance for the development and the exploitation of the set of meaningful information about platform users, in terms of screening and interaction with the functions of the C-MMD Platform.

One of the functionalities of C-MMD platform is, indeed, to provide reliable, meaningful, structured and personally experienced information and feedbacks to be processed and used by the Health and Social professionals as well as by the platform itself to continue the process of provision of tailored and personalised services.

D1.5 introduces, therefore, a proposal of C-MMD Summary Report (SR), in line with European recommendations as well as national requirements, and responding to the interoperability specification in order to act as an instrument for an integrated caring approach to the PLWD and the caregivers. The C-MMD SR is sourced by data and information gained by the services and functionalities of the C-MMD platform (profiling, screening, on-line interaction, gamification, tailored intervention, preferences) as well as by the collection of feedback regarding users' satisfactions and expectations; it benefits from the customisation of the information gathered in terms of personalisation and customisation of the treatment provided by the platform to its users (in connection with D2.2. Customisation guidance document –CAREGIVERSPROMMD 1st version); it then results on summary of multi-disciplinary information allowing health and care professionals entering the C-MMD platform to access relevant information and to make decision at the point of care.

The C-MMD SR represents the result of a process which begins with the user profile, and continues with the screening performed by health and social professionals (offline) and by the Platform itself (online); the overview created by such a process integrates also the results of monitoring the online activities and behaviours of the users and it take into account also the preferences expressed by them online.

The C-MMD SR has two main objectives: (1), to provide meaningful data and information to maximise the customisation and personalisation of C-MMD platform services towards PLWD and caregivers; (2) to be a multi-disciplinary and interoperable tool to identify users' status and to be integrated in the future system of Electronics Health Records.

The Deliverable is expected to provide information to technical work packages within the project, particularly WP2. It has, as said, a strong interconnection with D2.2. Customisation guidance document –CAREGIVERSPROMMD 1st version, which is a deliverable describing, from a technical point of view, how such a Summary will be translated into digital language adopting existing technical standards to facilitate its interoperability, and D3.2 APIs for integration with the 4 clinical partners' IT systems that provides the technical implementation of such standard through the API description.

2 State of the art: toward the integration to EHR standards

C-MMD Platform is expected to provide information about the health and social conditions of PLWD and caregivers who shall be integrated into electronic records system, with the purpose of integrate the general health picture with a tailored and specific insight on MMD and MCI. To do this, C-MMD platform has to provide an output which adopts the same standards of existing Electronic Health Record (EHR) systems, adopting languages and technical requirements that can ensure the interoperability with national NHS systems.

2.1 Models of records

The introduction of Medical Records has started, since the 80'eighties, with the aim of supporting health professions to better take care of people; it has been focusing the organisation, the systematisation and the management of health information, involving technicians, health decision makers and national governments, as well as health managers and professionals. The idea behind the first approach of Medical Records was the transfer of paper-based health information to ICT-based tools, focusing on commercial strategies and leading to some examples of failure of implementation. So different MRs are have been produced with different aims and responding to different needs.

Electronic Medical Records (EMR): is under the custodianship of a health care provider(s) that holds a portion of the relevant health information about a person over his lifetime. The approach is that of provider-centric or health organization-centric health records of a person. Hospital wards and professionals mainly use it, as it is the record for the management of specific disease and of medical specialities. The focus of the record is the management of clinical information related to specific disease and not the longitudinal clinical data of the user.

Electronic Health Records (EHR): represents the longitudinal record of the user, as it is a complete health record under the custodianship of a health care provider(s) that holds all relevant health information about a person over his lifetime. The approach is that of a person-centric health records, which many approved health care providers or health care organisations dealing with the health of the user can use. It contains health relevant data of the user, including information about wellness, life style and nutrition, collected by different encounters in different organisation, with the purpose of supporting continuity of care, education and research.

Patient Summary (PS): is the record reporting summary clinical data and health information of the patient; it is used when it is not possible to access the complete health and clinical information (EMR or EHR), generally in emergency cases or when detailed data is not available. The approach gives the opportunity to provide a summary of key health information to be accessed by clinicians anywhere. It can be considered as a part of EHR, but is deeply different from EMR, as this contains specific clinical information or specific disease data of the patient used in hospital ward or medical department.

Personal Health Record (PHR): is a new concept introduce in the USA, based on the approach of involving and enabling the patients to interact within the health area; it foresees the opportunity for the patient to interact directly with the health professionals and, eventually, to add directly personal health information and details, in order to let clinicians better understand the habits and the lifestyle of the patient. PHR is defined as an electronic application through which patient can access, manage and share their health information and that of others for whom they are authorised; the ideal framework is that of an "interconnected" PHR.

2.2 EU forewords

The contribution of the European Union in the promotion of the research and the innovation in the Health area, has allowed reaching remarkable progresses in terms of impact and effectiveness, also in the framework of medical records

.As prior and essential framework, the Directive 95/46/EC (1995)[1] on the protection of personal data and free movement of such data represents the legal basis for using personal health information; according to Article 8 of the Directive, the legal foundations for using personal data will be the explicit consent to the processing of data (Article 8 (2) (a)), vital interests (Article 8 (2) (c)) or the necessity for healthcare purposes (Article 8 (3) (b)).

In 2008, the EU Commission published a Commission Recommendation (COM(2008)3282 final) on cross-border interoperability of electronic health record system, trying to handle the proliferation of incompatible ICT formats and standards in healthcare due to recent developments in ICT systems and services of EU Member States; the main consequence of such a lack of interoperability causes problems for travelling EU citizens and for EU health professionals who might treat them.

In 2011, the Directive 2011/24/EU recognised the exchange of clinical information of the user as fundamental requirements for achieving a cross-border healthcare, identifying in the PS the tool for the exchange of health information; then, the PS become a prior information asset when an individual accesses health services in a different EU member state, as emergency as well as planned care. Pursuant to article 14 of Directive 2011/24/EU, the eHealth Network was set up to facilitate the cooperation between the European eHealth systems and to draw up a series of guidelines to facilitate the cross-border transferability of medical data.

In the end of 2012, the Commission adopted a new Action Plan 2012-2020, proposing a series of measures and expressing its commitment to remove the existing barriers to a "fully mature and interoperable eHealth system in Europe".

In November 2013, the DG Health and Consumers and the DG Communications Networks, Content and Technology proposed the "Guidelines on minimum/non-exhaustive User Summary dataset for Electronic Exchange", representing the fundamental step to proceed

[1]The upcoming EU regulation regarding personal data (General Data Protection Regulation - GDPR) will supersede the current Data Protection Directive (95/46/EC) from 25 May 2018.

with the implementation of the Directive 2011/24/EU on the application of user's right in cross border healthcare.

Research and innovation leading activities in the field of eHealth are the European Large Scale Pilot "European Patients' Smart Open Services" (epSOS[2]), the Thematic Network "CALL for InterOPErability" (CALLIOPE Network[3]) and the eHealth Governance Initiative (eHGI), providing solid and reliable foundation for the progresses of cross-border health and for the guidelines for the Patient Summary.

2.3 Requirements for interoperability

As mentioned in the Commission Recommendation of 2nd July 2008, the **lack of interoperability** is a sensitive and problematic issue for the use of electronic health record systems. Fully interoperable electronic health record systems should ease the access to users' information, enhancing the quality and safety of user care and ensuring accuracy and safety of user data.

The interoperability is fully addressed by the "Guidelines on minimum/non exhaustive Patient Summary dataset for Electronic Exchange", that is defined in Article 1 (2) as essential to the provision of high-quality care, and therefore asking the full engagement of Member States to take appropriate measures to make their respective Patient Summary datasets interoperable, both technically and semantically.

Interoperability of EHR systems involves transfer of personal data concerning a user's health. These data should be able to flow freely from one Member State to another, but at the same time the fundamental rights of the individual should be safeguarded. With the Commission Recommendation and the Guidelines, Member States and their relevant bodies are equipped with the basic principles on how to address interoperability in a cross-border setting, applicable eventually as concerning a cross-disciplinary and cross-sectoral health and care environment.

As concerning the interoperability of EHR systems, the recent "*Guidelines on minimum/non exhaustive Patient Summary dataset for Electronic Exchange*" address the following objectives:

1. To outline and to settle the principles for the broad agreement and engagement as regard to cooperation on shared and interoperable eHealth information;
2. To enable interoperability between health information shared among different healthcare systems, possibly making use of existing standards (ISO) and being based on the approaches and achievements of relevant initiatives already providing interoperable and viable outputs.
3. To face and to solve the challenges of interoperability of EHR systems, building appropriate networked systems and services supported by appropriate legal, regulatory, medical and care requirements.

[2] (http://www.epsos.eu)
[3] www.calliope-network.eu/

3 C-MMD process for the creation of a "Summary Report"

According to services currently implemented into the platform and tested for by the usability evaluation, the C-MMD platform enable is able to monitor the activities of its users (of PLWD and caregivers, by Health and Social Professionals) and record their behaviours, psychological and health conditions, in order to evaluate their status; also the platform can record the scores of online questionnaires filled in by users, the screening results and follow-up of the treatment adherence. All these this raw data made available by in the platform will have to be processed and organized into a usable set of information for health and social professionals' analysis. The reported data will fill in a unique report containing different sections, one for clinical interpretation and another for social interpretation. Finally, they should be integrated in the existing systems for sharing medical data; to facilitate the decision-making process for more personalized interventions.

3.1 Data sources

The C-MMD SR is expected to identify PLWD, caregivers and dyads health status, social conditions, weaknesses strengths and difficulties, in order to generate health and social information able to allow the Professionals to plan interventions. These resulting data are also meant to be used to update health and social report, possibly through EHR system (T1.6). From a more general point of view, the Screening Strategy within CC-MDD project and platform is expected to provide consistent and valuable assessment outcomes from the profiling and from the monitoring levels screening, aiming to allow the contents adaptations and the professional personalised interventions.

Therefore, the SR will be generated by the collection of raw data derived from different sources; at first, the **user's profile** itself, which provides information on the demographic and living conditions of each user, the dyad's status, and level of memory problems experienced e.g. MCI or mild dementia. Educational level, working conditions, home structure, and other profile information can be made available as an optional. Other key information comes from the screening process, which, according to the **Screening Strategy** described in D1.3 is double: offline screening performed by Health and Social Professionals using scales; then the online screening, the monitoring process performed within the platform using as a tool online screening scales submitted as questionnaires. Other sources of information to be considered are the **treatment adherence**, that is meant as a monitoring of *if* and *how* the user followed or not the set of interventions she/he has been asked to perform. Then, the **users' preferences**, the satisfaction for contents provided, the "*likes*" and the "*dislikes*" expressed. Finally, the **users' interactions**, which means the level of participation, the discussion joined, contents shared and the achievements reached (gamification). The expected results of the C-MMD Screening Strategy is the interaction of different actors (Dyads and Health and Social Professionals) in the platform, allowing the achievement of a coherent personalisation of the interventions and confirming the bottom up and multidisciplinary approach of the project. The following table organises the mentioned list of data sources and shows the connection of the chosen approach with the

previous documents of the project. Information provided by user profiles shall contain some usability information, as those organised in D1.1, and they shall be derived from the Profiling level of the Screening Strategy as defined in D1.3.

The Screening of the users will generate scores from the questionnaires and scales used to monitor their symptoms and the behaviours. The scales are classified and organized in the documents D1.2 and D1.3. Treatment Adherence is described in D1.1, while the importance of users' preferences and interactions for the creation of tailored and personalized contents in D1.4.

Table 1. Sources of data and information to be included in the C-MMD Summary Report

References	Sources	Meaning	Reported data
D1.1 D1.3	Profiling	Demographic information	Basic info
D1.2 D1.3	Screening	Scales	Scores
D1.4	Preferences	list of interventions and user's evaluation	List of preferences
D2.2	Interactions	Frequency, quality and quantity of interactions with non-pharmacological treatment	Performance/ Gamification scores
D1.1 D3.1 D3.3	Treatment Adherence	Adherence to pharmacological treatment	Prescribed therapy and adherence rate

Here follows a detailed description of each source.

3.1.1 User's profile

PLWD. Profile information: demographic information, such as age, gender, education; contact details, living conditions (where she/he lives and with whom), relationship with the caregiver; neuro-cognitive status initial level, comorbidity symptoms, treatments, physical impairments (audio-visual).

Caregiver. Demographic information, such as age, gender, education; contact details, living conditions (living with PLWD or not), relationship with the PLWD, frequency of care provided; peer support.

First and last names, spoken language, nationality, date of birth, and their gender are information collected. Living conditions may be relevant for a better understanding of the users' social support: who do they live with or if they live in private premises or in sheltered

accommodations benefiting of professional care need also needs to be collected (It could be interesting to know part of PLWD at home (asset/liability…) and within family relations, rules of caregiver (administrative, financial, activities of daily living…). Are there other secondary caregivers and what do they do? To add educational level and work (current or past). Both for PLWD and caregivers, their profiles may reveal useful information for an initial sketching of the individual and also information about the dyad dynamics: the strength or the weaknesses of the relationship between caregiver and care receiver can change the direction of the process to select a suitable the proper intervention and provide information to the professionals when defining the tailored and personalised intervention strategy.

3.1.2 Screening

PLWD. Neuro-cognitive level, scores of online and offline scales; comorbidities, treatment adherence.

Caregiver. Scores of online and offline scales; stress, depression, reactivity, impairments, etc.

According to the Screening Strategy described in D1.3, the C-MMD platform can monitor the users' health and social conditions by submitting online scales whose results can be read by experts in order to support their decision-making about the intervention strategy or changes in treatments. Scales represent a tool with a double scope: reveal users' conditions according to the scores they reach, as well as to test the users' capability of interaction with the platform, creating motivation and engagement (via gamification).

This periodic screening generates data that can be added (summarised) in the C-MMD SR. This data can be classified by domains: *Clinical and cognitive scales* revealing changes in the cognitive status and wellbeing of the PLWD and the Caregivers' stress; *Psychological and behavioural scales* providing data related to depression symptoms, anxiety and significant changes in mood that can affect the interventions and the treatment planned. Caregivers' depression symptoms can be measured also, as well as their positive goals in care activities: such data can assist the decision making of experts in relation to support required.

Functional scales and Quality of life assessments provide an important addition to screening with their focus on actual ability rather than presumed capacity. A person's ability to complete activities of daily living has clear implications for their quality of life, and therefore the interventions and the treatments may vary accordingly.

Health related scales allow monitoring of the health conditions, both for Caregivers and PWLD. Scales submitted by C-MMD platform generate scores that are integrated into data already accessed by health professionals; in this scenario, professionals benefit from the SR in terms of continuous screening and monitoring which can aid their decision-making. In addition, the *Treatment adherence* is monitored, and consequently the success and suitability of the treatment approach can be evaluated too.

Dyad's relationship assesses PLWD and their caregivers' quality/strength of relationship. This brief self-report measure can introduce into the SR specific needs of social and psychological nature for both members of the dyad.

3.1.3 Preferences – Recommender System

- PLWD. Preferred Intervention domains, contents consumed, contents liked; contents disliked; visual preferences;

- Caregiver. Preferred intervention domains, contents consumed, contents liked; contents disliked; visual preferences;

The personalization of interventions within the platform is allowed by a Recommender System that define meaning, scope, forms, and shape of platform contents according to users' needs and preferences. From this point of view, the SR shall somehow deal with the preferences of users, as they have to be taken into account to decide about further more tailored interventions, as well as they allow the understanding of users' online behaviours that are significant insights to evaluate residual abilities and capability to socialize and remain active. The data collected reflects the health and social domains that the user prefers to receive support about, the health and social domains established as goals for their healthcare professionals, the amount of interventions received, the domain areas, the amount of those interventions that were actually accepted by the user, the satisfaction level and precision of the recommendations.

Viewing the recommender system as an important step in the personalization process, the type of the user (Caregiver, PLWD, etc.) and the personal medical information will be taken into account before presenting to the user highly personalized recommendations for available interventions. In the reverse, the participation of the users in the proposed interventions as well as their performance -when available- will be taken into account for decision making on the interventions strategy. Additional data like the rating they award the intervention and the level of user's satisfaction can be taken into account for the evaluation of the interventions themselves in order to have a good fit between medical conditions, personal preferences and required treatment.

3.1.4 Interactions

- PLWD. Frequency and quality of posts; frequency and quality of interactions with caregivers and other friends; discussions joined; communication with the General Practitioner.

- Caregiver. Frequency and quality of posts; frequency and quality of interactions with friends and peers; frequency of request of help; discussions joined; communication with the GP.

The C-MMD Platform is able to provide interventions, both to PLWD and to caregivers, within physical, cognitive, social and psychological domains (see D1.4 for more details). An

intervention, in this case, can be considered as a set of contents provided by the platform and aiming to screen symptoms, monitor users' abilities and reactions, allow the professional intervention of expert. So it is significant from both the social and the clinical perspective to have a report on how a user is able to react to such interventions: data about the acceptance or the refusal of a given intervention can be relevant, (1) to understand the status and the care needs of the single individual, and (2) to allow the evaluation of the treatment within a significant number of users. In the first case, this data allows professionals to re-define and customize the intervention strategy, while, in the second case, they provide insights for statistical and research purposes.

Such an interaction is subject to user's monitoring and thus the involvement of users in a given intervention will be reported as well. The degree of participation will be expressed as a percentage of the actual participation to the expected participation, and from those interventions which can report participants' performance (e.g. the playful interactive interventions performed in the C-MMD platform as additional C-MMD apps).

Additional information like the time needed to complete tasks and the success rate will be reported for statistical purposes and for customisation of the personalised intervention strategy.

Overall, the non-pharmacological interventions will be part of the SR by adding the information presented in the following table. None of the following data types is mandatory; the available data will be reported where they are available.

Table 2. Data from the non-pharmaceutical interventions to be reported in the Summary Report

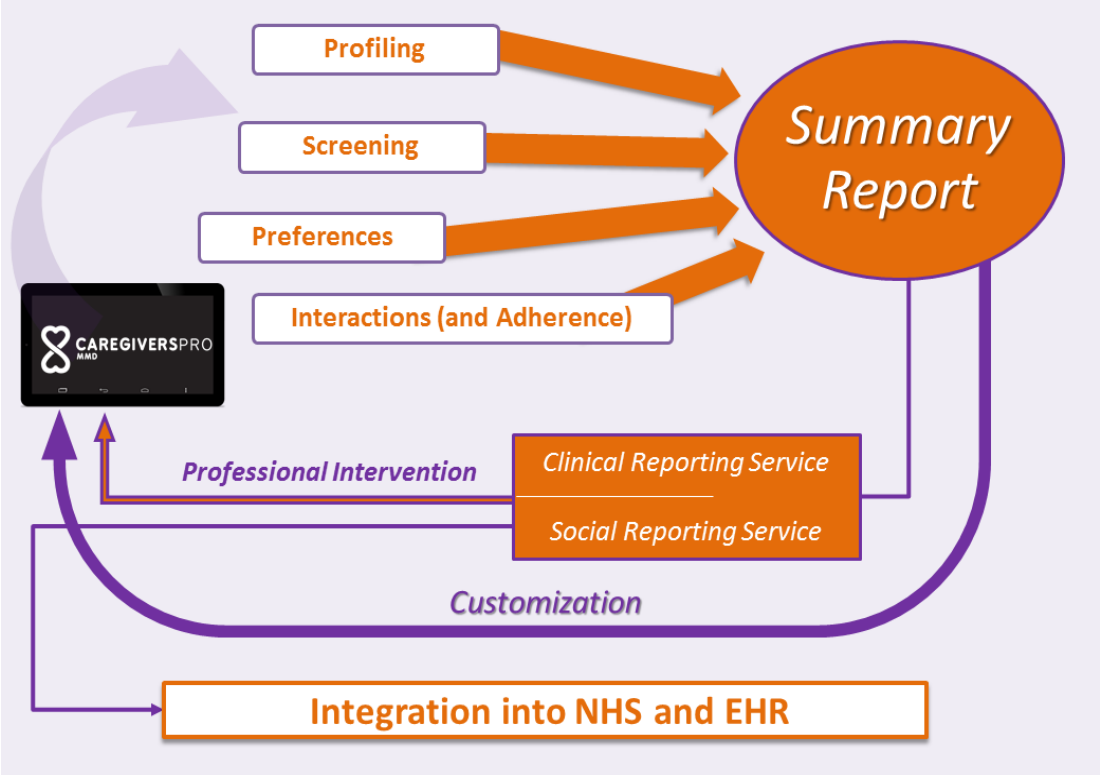
A/A	Name	Description	Type of Data
1	Participation	Numeric descriptor for the degree participants followed instructions on the frequency of use	Percentage (%) calculated as the actual participation to the expected participation.
2	Duration	The time needed to complete the intervention in seconds. For very long interventions (e.g. music therapy) days or hours may be reported.	Integer number and measurement unit
3	Score	The total number of points earned by the participation in the intervention (gamification) in relation to the level of difficulty.	Integer number (points)
4	Average response time	Each response in subtasks will be recorded and finally the average response time will be reported for statistical reasons	Float number (in milliseconds)
5	Success Rate	Numeric descriptor for the success rate	Percentage (%) calculated as

		(i.e. satisfaction indicator)	the points earned by the activity to the maximum possible points

The following figure aims to describe the process by which the raw data will fill in the SR; then it explains how the Report will allow professionals to have a view of the users conditions from the clinical as well as the social points of view, and consequently provide, via the platform, their professional interventions, after the due consultation (third level of the C-MMD Screening Strategy, as described in D1.3); the report, therefore is the product of the screening of the users status and the results of the users' reaction to the treatments: so it provides professionals with data that they can read and manage in order to decide about the further provision of interventions; according to the report, professionals may be able to decide if the treatment has to be replicated, modified or changed.

At the same time, the Report aims to be meaningful and compatible with different systems of electronic medical/health records; it means that it has to respect some format, language and security criteria, in order to contribute to improve the quantity and quality of information about a person digitally shared among integrated systems, with the final scope of a more personalised and tailored provision of care services.

Figure 1. Dataflow to create the Summary Report



3.1.5 Treatment Pharmacological Adherence

PLWD. Therapy Adherence Rate.

Caregiver. Therapy Adherence Rate.

As part of the gamification strategy, the platform allows the monitoring of users' adherence to therapy treatments. As from D1.1, adherence to treatment is the extent to which a user follows a prescribed therapy in terms of time plan and recommendations (of the prescriber). The raw data that CCMMD platform can generate about this aspect are related to the Adherence Rate, valid both for PLWD and Caregivers. Clinically and socially relevant information about adherence can be the identifications of gaps in therapy: such information may be useful to be reported in the SR.

3.2 Expected results: Interviews with health and social professionals

To define what the C-MMD SR should contain in order to be meaningful and interoperable, the viewpoints of health and social professionals have been collected during face-to-face interviews. A psychologist and two neuro-cognitive specialists have been interviewed. The three ladies will be involved in the incoming pilot studies in Italy.

According to the opinion of the **Psychologist** (met on 17th March at COOSS premises), the scope of the SR is to be a working tool that can guide the periodic visits she has with her users. For these purposes, the document shall contain personal information, in particular, the living conditions and if any changes happened in this domain, as well as the initial diagnosis.

Then, as a psychologist, she asked to have a view about the level of Depression (or anxiety, or well-being), as another relevant item to be included in the SR, both from a social and clinical point of view. The user's mood adds further information about the user condition: the feelings, the attitude toward coping with the illness, the attitude towards the care received are key aspects that may affect the proposal of interventions.

Information about interactions with C-MMD functions may describe the acceptance of the interventions and the satisfaction towards the proposed contents. It allows experts to know how often the user performed the tests/exercises/scales, if they have been completed or not. Scores should be reported, as well as the user's appreciation and attitude toward them. Rejected interventions have to be reported too. A register of missed clinical appointment can be also helpful.

A Social Report integrating this data can trigger interventions aimed at stimulating the cognitive domain, proposing contents aimed to:

- enhance memory, concentration, spatial and temporal orientation, self-control;

- improve mood through positive communication, manage anxiety, reduce depression through positive and joyful contents;
- improve/maintain adherence, which means to keep monitoring the progress of the illness and adequate interventions to the users' changed conditions. Scales, tests and exercises shall be adapted to the new users' conditions or confirmed if the scores obtained remain constant.

The two **neuro-cognitive specialists** (met on 21st March at the Ancona Hospital) suggest that the SR should be accessible from each user's profile, and it should report two main areas of contents, that they called " "*Activities*" and "*Cognitive capabilities*".

Area called "*Activities*": this area, they suggested, should report about online activities; it should list activities per dates; for each date the number of activities performed should be shown, then the duration of each access, and the number of tasks completed.

Here is an example of the "*Activities*" Area of the SR.

Name: **Mario Rossi**[4]	**Category:** **PLWD**	**Age:** **73**	**Gender:** **Male**	**1st Contact:** **01/01/2017**
Activities				
Dates	***N° of access***	***Duration***	***Tasks completed***	***Time needed***
01/01/2017	*3*	*60 min*	*3*	*20 min*
02..	*5*			
03…	*4*			
…	*…*			
31/01/2017				

The second Area, called "*Cognitive capabilities*" should report the scores of the scales that the users reached in a given period. According to the clinical experts' expectations, scores shall be reported in absolute values, as well as in a meaningful way for non-clinicians: for example, the GDS scale scores shall be indicate in absolute value (i.e. 14) and also the interpretation of the number shall appear (i.e. 14 = "Mild Depression"). This approach should be repeated for each scale used online.

The clinical experts drafted this second part of the SR as follows:

Name:	**Category:**	**Age:**	**Gender:**	**1st Contact:**	

[4] All names used in the examples are fictitious.

Mario Rossi	**PLWD**	**73**	**Male**	**01/01/2017**	
Cognitive capabilities					
Dates	***ACE-III***	***GDS***	***EQ5D***	***PHQ9***	***Etc.***
01/01/2017	*84/100* *Memory problems*	*14* *Mild Depression*	*85* *Good generic health*	*19/27* *Anxiety over the average*	…
02..					
03…					
…					
31/01/2017					

Scores and results may be also represented graphically. Graphics may support the identification of symptoms, as well as allowing the evaluation of tasks performances, visually representing any positive or negative "*peak*", which may also suggest whether the user is acting alone or being helped by others (for example, if a user has recurrent scores in performing a task but suddenly a peak of performance is evidenced, then it may mean that he or she let someone else completing the task, for instance a nephew, i.e. for games).

The SR, shall also compare results with scores obtained in the month before, or, at least with the previous SR downloaded. This comparable data may be very significant from clinical point of view, to evaluate if parameters are stable or they are changing.

Clinical experts, stated that there is additional information that may have clinical impact and therefore they would be useful to be reported in the SR. Namely, they suggest to report about the "Usual Network" which means the number of online contact each user have, and the number of persons available around the person (offline contacts). These data may be reported within the Profile area of the SR.

Also, if possible, small amounts of information about the physical activities (such as walks) may be meaningful for them (even if it is not clear if and *how* the platform could register data about it).

Clinical experts also went through the Pharmacological Treatment issue: from their perspective, it is not relevant to know which medicines users are consuming, but may be useful to know the nature of the pharmacological treatment, which means, for instance, to know if the users are receiving an "anti-Depression" treatment, or "anxiolytic" treatment, or

"memory" treatment. They confirmed that the SR might be enriched by information like this.

SR shall report comorbidities too.

4 C-MMD User Summary Report

Following the previous description of data collected and processed by C-MMD platform, and in the perspective to match the experts' expectations, the present section provides the main features and requirements of a proposal of the C-MMD SR, as a way of returning and reporting health and social information about PLWD and caregivers that health and social professionals can manage and process, within an integrated care system. The C-MMD proposal of SR is aimed at integrating the existing standards of health reports in order to improve the decision-making process about further and more customised interventions.

The main goal of the C-MMD SR is to improve the user's support and treatment, by supplying relevant, specific, targeted and customised information to be used by the platform itself for the optimisation of the personalisation process, as well as by Health and Care Professionals for the implementation of a more effective and integrated Care Plan. Within the framework of C-MMD platform, the SR offers an integrated and comprehensive view of health and social information related to MMD and MCI of the PLWD and related to burden and quality of life of the caregiver, including information that they generate themselves through the interaction with the C-MMD platform and information from Health and Social professionals related to diagnoses and test results. It takes the form of a specific informative tool, based on user-centred approach, gathering a set of relevant and meaningful information about MMD and MCI related issues, as well as wellbeing and quality of life in general, from a range of sources.

The aim of the C-MMD SR is to provide not just a static repository of data, but to combine information, knowledge and platform feedbacks, in order to facilitate the integration, the coordination and the continuity of health and social support to PLWD and caregivers, at the point of care. It is conceived as a tool to be integrated with the EHR system, thus providing greater benefits than stand-alone systems.

4.1 Structure

C-MMD SR aims to provide the Health and Social Professionals with a dataset of essential, understandable, customised and targeted socio-medical information, available at the point of care. Namely, C-MMD SR is a set of essential user's data with an impact in relation to MCI and MMD (when dealing with the PLWD) or to burden and psychological distress (when dealing with the caregivers), able to provide the Health and Social Professionals with:

- User's general information (from profiling)
- User's clinical and social information (from screening and intervention strategy)
- User's attitudes and preferences (from on-line interaction and recommender system)
- User's medication information (from profiling/ Treatment adherence service)

The CC-MDD SR is presented in a structured way, through structural modular data groups or sections, each of them containing a related set of information, in order to facilitate the

understanding of the whole picture, to integrate a holistic picture in the planned and integrated care process and to manage separately any subset.

Actors involved in the C-MMD SR services are the following:

- users (as conceived in the framework of the EHR or PS/User Summary): those are the PLWD and the caregivers, receivers of the supporting services of C-MMD platform;

- Health and Social Professionals: those are the supporting professionals from the clinical and social side, accessing the platform and contributing to the implementation of the C-MMD services towards PLWD and caregivers;

- Health and Social System: it represents the institutional actor, generally the public entity in charge of the governance of the health and social care in a specific area or territory (e.g. local health agency, social district, etc.); it does not access directly the C-MMD platform or services or SR, but it is complementary as for the interoperability with EHR.

4.2 Functional and Non-functional requirements

The potential of exploitation of C-MMD platform relies also on the possibility of the C-MMD SR to complete, integrate and add value to the potential of information of EHR, covering different types of EHR (as defined by the Commission Recommendation of 2 July 2008), especially those designed for a shared access and an integrated system of health and social care.

Therefore, based on Commission Recommendation, on "Guidelines on minimum/non-exhaustive User Summary dataset for Electronic Exchange" and on Directive 95/46/EC, the following functional and non-functional requirements of the C-MMD SR are outlined.

Table 3. Functional and Non-Functional requirements of C-MMD SR

Functional Requirements	Non-functional Requirements
The users must be unequivocally and uniquely identified in a trustworthy way to allow the Health and Social Professionals to consult the information related to them (following informed consent).	The service must be accessible and usable when needed and requested, so technical unavailability must be detected and solved.
The Health and Social Professionals must be unequivocally identified and authenticated in the C-MMD platform, according to their role and profile.	The communication (passage/exchange of information via the platform) must be secure and protected, and the integrity of information must be guaranteed.
The users must provide informed, specific and independent (freely) consent and consent lifecycle must prove the evidence of its legitimacy.	The information must be meaningful to the information needs of the Health and Social Professionals, to be appropriately interpreted, treated and processed for further care steps.
The information in the C-MMD SR must be structured through modular data groups to facilitate the understanding and optimise the treatment/management.	The information must be meaningful to the customisation process of the C-MMD platform, allowing the Health and Social Professionals to adopt more consistent

	decisions and follow up.

4.3 User Consent and Access

As concerning the user consent to the creation/sharing/extracting/elaborating of C-MMD SRs information, the following possibilities /options should be considered:

- To ask for explicit consent or 'opt-in': where the SR can be created and data included only with the expressed consent of the user;
- To ask for implied consent or 'opt-out': where the consent is presumed, unless the user explicitly refuses it.

Through the informative consent process outlined by the whole services of C-MMD platform, the platform users receive all appropriate information (see WP4 methodology for Pilots preparation for more details), entering in the 'opt-out' option; for the implementation of the C-MMD SR, and namely for the potential integration with EHR, further evidences of "informed consent" (information, understanding, awareness, competence, independence) are needed, namely about:

- The kinds of information that are being recorded and retained

- The purposes for which the information is being recorded and retained

- The protections that are in place to ensure the non-disclosure of their information

- The kinds of information sharing that will usually occur

- The choices available to them about how their information may be used and disclosed

- Their rights to access and where necessary to correct the information held about them

Directive 95/46/EC requires that data processed must be adequate, relevant and not excessive in relation to the purposes for which they are collected and/or further processed. The approach is therefore oriented to the "need-to-know" and the access should be role-based and limited to persons needing the access, up to the definition of different categories of access for different health and social professionals. This can be ensured by assigning different rules for different types of health and social professionals, (health data for the clinicians and social data for the social) or assigning to the platform users (PLWD and caregivers) the task of deciding which professionals have access to which data.

The definition of the access rules also entails the users' rights over the data and therefore their consent, in terms of: access the data, to erase and correct data; know who have accessed to their data. And the possibility for the health and social professionals to be notified that some data is missing, in order to ask the users to provide the missing data. Furthermore, information harmful to the users should not be directly available to them, leaving to the health and social professionals the decision about when, how and to who (PLWD and/or caregiver) communicate the delicate information.

4.4 Contents

Determining what information should be included in the C-MMD SR requires balancing competing interest. On the one hand, having in mind the interoperability and complementarity with EHRs system, full health data should be provided, allowing health professionals to provide a better overview of the users' health; on the other hand, some of the medical information can be particularly sensitive.

The primary driver for deciding on SR content must be *User Care*, that is the implementation of a tailored, personalised and user-centred approach. The C-MMD should be able to collect data and information, to be used for many purposes under a multi-disciplinary approach: to adapt intervention strategies, to monitor performance, to adjust treatment plans, to recommend contents, to provide supporting evidence and to compare results. Being a tool devoted to a multi-disciplinary approach towards MCI and MMD, the C-MMD SR also should be able to collect, elaborate and then report information about:

- Judgements about the user's needs and problems
- Care planned and provided
- Results of assessments
- Views, expectations and preferences
- Decisions made
- Communications (with users and carer and other professionals)

The framework of contents for the C-MMD SR is limited to the set of data gathered and collected by the platform itself (profiling/screening), thus elaborated and processed to provide adequate, relevant and meaningful information related to the treatment and monitoring of MCI and MMD.

4.5 Evaluation

The evaluation of the C-MMD SR service has to be foreseen, in order to ensure the monitoring of its functionality by PLWD and caregivers, and especially the related interoperability provisions by Health and Social Professionals; in the evaluation process, it is necessary to review progress achieved through the C-MMD SR on organisational and technical aspects.

Table 4. Dimension for evaluation of the C-MMD SR

Dimension	Description
Service	General usefulness of the service
Acceptance	Degree of acceptance of the service by actors (see 4.1)
Usability	Usability of the designed process (maturity of EHR systems)
Infrastructure	Coverage of infrastructure for the service at the actors site (interoperability design evaluation)
Content	Completeness and usefulness of data (usefulness of specific

	and tailored views on the whole data set compared to specific datasets, within the multi-disciplinary approach of MCI and MMD)
Security and Privacy	Perceived security of the service and privacy of data
Consent	Willingness to give consent

5 Technical Requirements: The Clinical and Social reporting service

There are semantic and technical issues (and a process to be standardized) in order to transform this report and its information into digital data that will be meaningful and interoperable. Ideally, C-MMD platform is expected to be able to provide information about users' health and social conditions. Such data to be collected and shared shall be *resumed* in an interoperable and meaningful way, in order to be integrated in existing health records. It means that C-MMD platform shall comply with recognised standards, which represent the only condition to allow the data exchange from a given system A to a System B. In D3.3, APIs for integration of gamification service, treatment adherence service and clinical report service, in the description of the treatment adherence service API it is stated that HL7 and especially FHIR standards are going to be followed. FHIR[5] is a standard developed by the HL7 consortium.

The following section describes the main functionalities and requirements for the C-MMD SR tool, conceived from the technological point of view as a report composed by 2 sections: the proposed solutions deal with a Clinical Reporting Service (CRS), a Social Reporting Service (SRS) and a Personal Reporting Service (PRS); these can be proposed as different sections within the SR, visible to experts who will can opt to hide a section and just open the most interesting for them. The ambition is to make the SR as a tool able to provide complex set of data in easy, comprehensible and meaningful way for experts with different expertise and competences.

The initial layout of the reporting templates (SRS, CRS and PRS) may differ to better fit the needs of the two groups of professionals, but it will be easy for both groups of professionals to create their own integrated approaches by combining social and health/clinical data in highly personalized views. In this way, personalization will be performed in both the contents of the report and the structure of the report. Consider the following two kinds of adaptation.

Content adaptation: Each professional will be able to access only the user profiles that are connected with his/her professional profile. After a request for accessing personal and medical data, professionals will be able to select from which users they wish to see data (select all users, specific users or only one user). *Figure 3. Design example of a new sensitive data access request* presents a design example of *how* a professional (either medical or social) can select the users based on which the content of visual analytics component will be adjusted to. It should be noted that professionals should ask for permission to access user's sensitive data, if not agreed earlier. The process of user selection is presented in the upper part of the *Figure 3. Design example of a new sensitive data access request*, while in the lower part the list of pending access requests can be seen. The button with the plus sign '+ ' triggers the creation of a new data access request as seen in **Error! Reference source not found.**. A search engine based on test entries is offered to professionals to help them select the right users from a long list of available users.

[5] https://www.hl7.org/fhir/

Figure 2. Design example of the content adaptation (user selection)

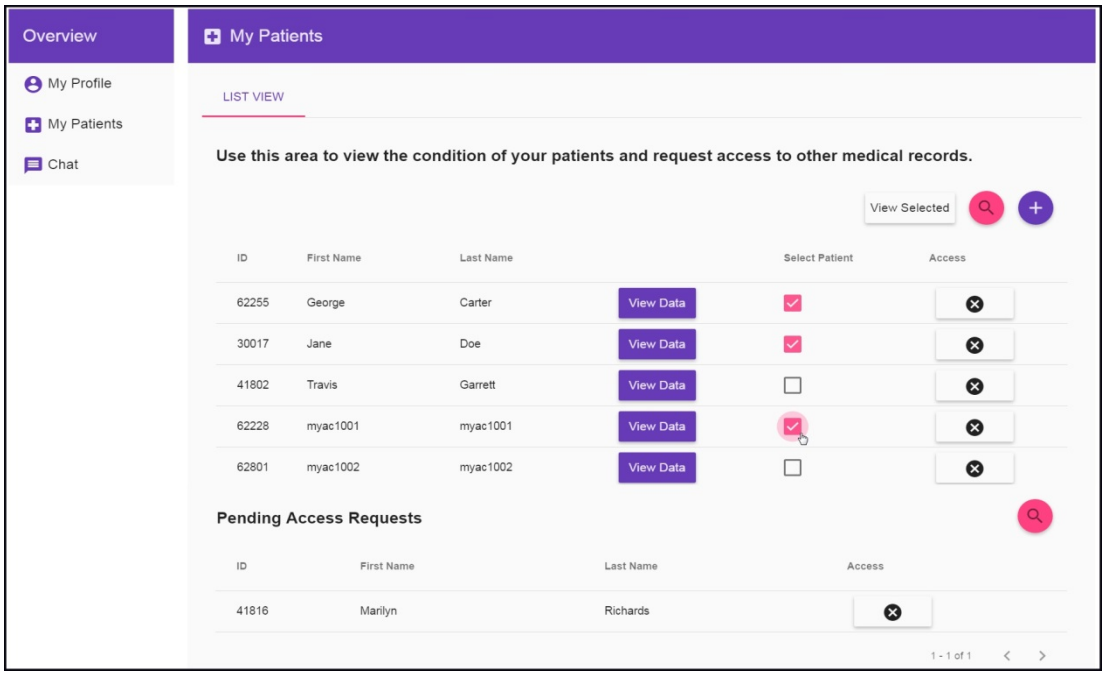
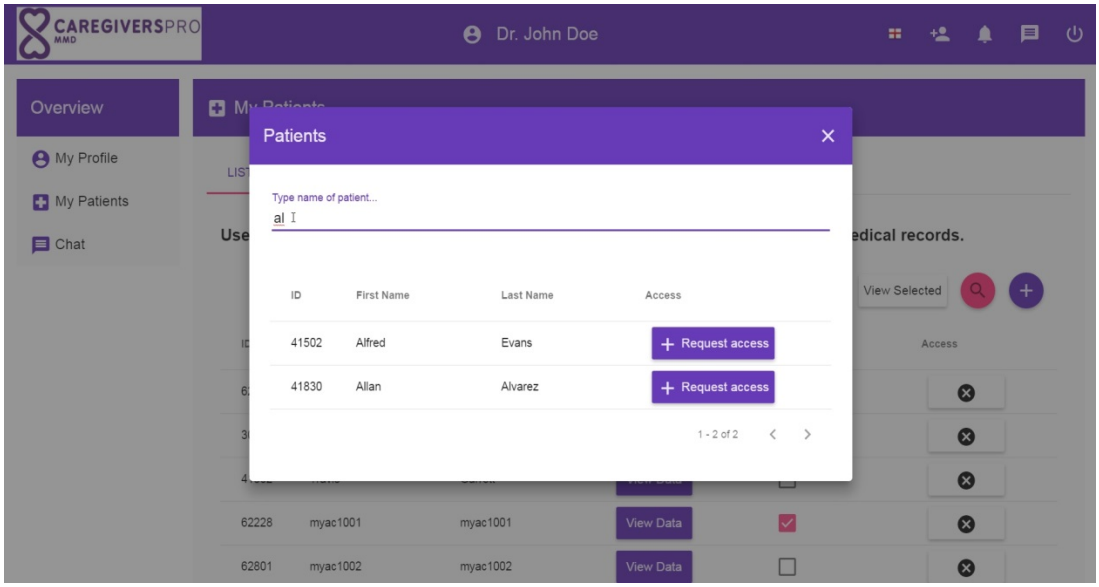


Figure 3. Design example of a new sensitive data access request



Structure adaptation: Professionals will be able to adjust the structure of the report depending on their needs and professional obligations. Professional profiles will be able to select any of the available social and medical variables to include in their reporting service. The concept of structure adaptation is explained in more detail in the following sections as two separate views of the Clinical Reporting Service (one for medical and one for social reporting). This kind of adaptation on reporting will allow professionals to select the types of diagrams and the types of variables they wish to view. The list of the available data (derived from the data model) appears as a list of select boxes. This way the views originally designed for social professionals can be exchanged with views coming from the medical professionals and vice versa. Another aspect of the structure adaptation is the way the information is displayed. On the examples presented up to now the user's data appear in charts and other similar forms of visual presentation. **Error! Reference source not found.** is an example of timeline used to present in time-dependent order the activities of the selected user(s). Each record presents a timestamp (date and time the intervention or other activity took place), a title to describe the type of the activity and other data related to the number of steps, the score of the activity, etc.

Figure 4. Design example of structure adaptation

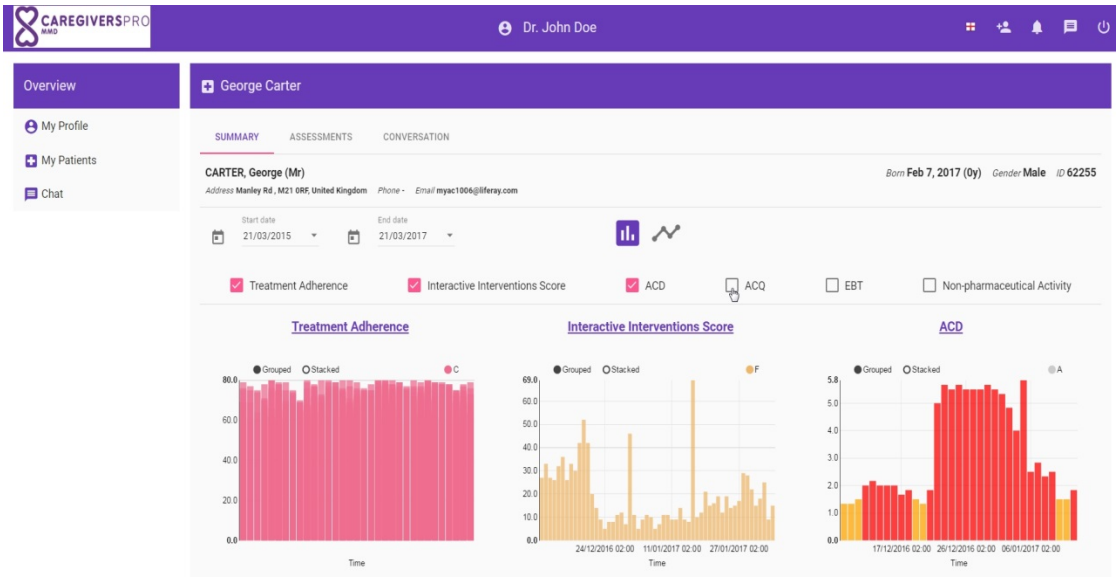
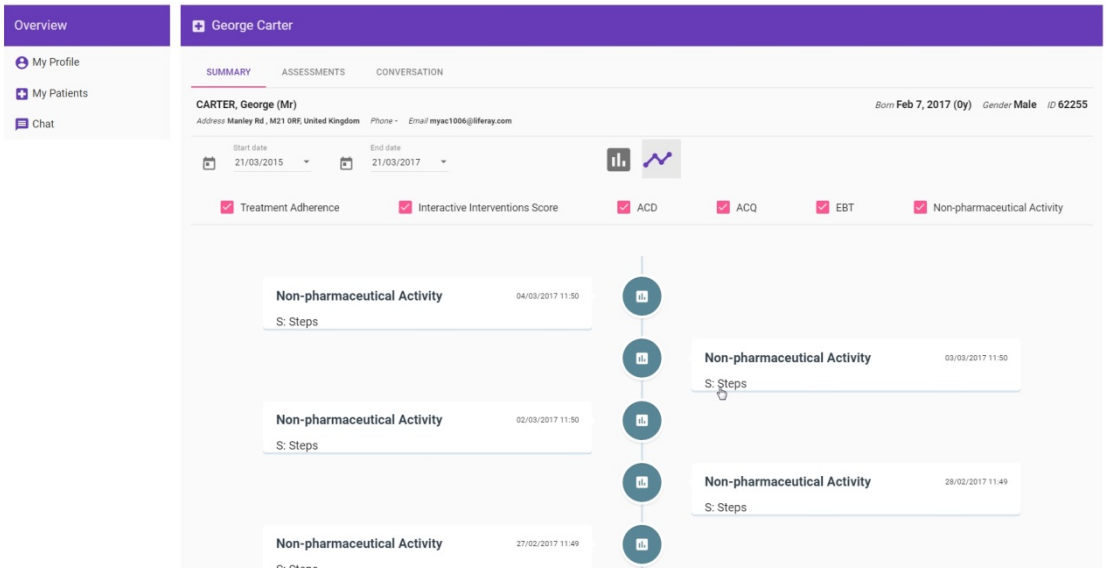


Figure 5. Design example of structure adaptation



5.1 The Clinical Reporting Services of C-MMD SR

The **Clinical Reporting Service (CRS)** will be offered to medical and social professionals who will maintain a regular professional account in the C-MMD platform and will access its functionality by using the very same credentials for accessing the platform. The CRS will be available only to C-MMD platform users who have been authorized as professionals and have under their professional responsibility the duty to monitor the user's medical and social status.

Based on the need of the C-MMD platform and the international literature on medical reporting (Di Croce et al., 2012; Larsson et al., 2003; Simon et al., 2005), the following principles will be applied:

1) There will be two similar, but separate clinical reporting services, one focusing on health and clinical issues and one more focusing on social issues;
2) The clinical reporting will be based on data collected by the platform, the scales and by the information already available in the medical profile
3) Professionals will have access to personal dyad's information and also access to the data produced by all PLWD and the Caregivers connected to the professional's account
4) The principles of Visual Analytics (Keim et al., 2008; Wong & Thomas, 2004) will be applied in both approaches in order to offer:
   - Machine information visualization
   - Analytical reasoning
   - Interactive visual interfaces
5) It will deal with complexity of the data and the heterogeneous data resources
6) It will not require any previous technical knowledge by professionals
7) It will be based on abstract data structures such as graphs in order to handle:

- High-level complex activities like user's social interactions
- Medical information coming from the sensing layer (validated scales)

8) It will allow comparisons between:
   - A user and a group of (similar) users.
   - The current user status and a previous medical state of the same user.
9) It will use statistical processes - performed automatically - to present future trends and sense risks (e.g. values out of range).
10) Showing respect to professional's time availability, the clinical reporting will allow professionals to have in short time a wide picture of all the people they support
11) It will amplify user's cognitive capabilities in the following ways:
   - Reduce search needs by depicting large amounts of information in limited space.
   - Represent the time-relationships of the data (e.g. by time series of time-related medical and social phenomena).
   - Allow perceptual monitoring of potential events.
   - Enable exploration of the data by changing parameter values (like time).
12) It will support the decision making in everyday user monitoring or in times of emergency by combining other sources and forms of medical reporting (external to the C-MMD platform) like narrative report produced by local in-house reporting systems.

Medical and social reporting by personnel will be provided as a highly effective mechanism for informing PLWD and their caregivers on their personal progress and at the same time keep evidence of this progress for future use. According to the results, an evaluation process may be triggered, restrictions may be applied, a new intervention may be proposed or no action may be taken. According to this, the CRS should pay efforts to:

1) Avoid any form of sensationalism in terms and graphics.
2) Be cautious with incomplete medical and social profiles and inactive periods.
3) Avoid forecasts of phenomena which cannot be fully described by the collected data.
4) Avoid making decisions only based on experimental data.
5) Consider the emotional impact of the medical and social reporting items on lay public (like the dyads) when shared with them.
6) Take into account local medical and social criteria and regulations.
7) Keep clinical reporting confidential and restrict the dissemination of health-related information through mainstream media (medical journalism).

Functionality descriptions

The CRS will use customizable report templates specific to the medical and social practice area to enhance reporting efficiency. This will allow a uniform way of clinical reporting to all the C-MMD professional users.

Description of the Available Data

Having a list of scales to be used in C-MMD platform (as derived from the WP1), we need to define how the scale results will be saved in the user model and in the medical records, no matter if the particular scales will be part of the C-MMD platform or not. Thus, both for scales implemented in to the C-MMD platform and for external resources that will be reported in the medical records in platform we need to indicate a basic set of descriptors. More specifically, from the technical point of view we need to know for each scoring variable the following:

1) The full name of the test, an abbreviation and a reference to initial authors
2) The type of scoring variable(s) (nominal, scale, ordinal, etc.)
3) The min and max values of each variable or the categories
4) The thresholds or the acceptance range for each one scoring variable (e.g. 28 and above is 'normal' for the Boston Naming Test. BNT is used here only as an example.)
5) Average time needed to complete the scale (administration time)
6) The frequency of their use in the C-MMD platform of in real world clinical settings (e.g. once per month, twice per semester, etc.).
7) The number of questions and/or parts of the test that should be reported separately. Some professionals pay attention to specific partial results, like the TMT-B part, or the BNT results with phonemic and semantic help.
8) The direction of the expected clinical status orientation (e.g. smaller test result indicates more positive test, or the opposite).
9) The order to give those scales (if any). For example, someone may need to take the A scale first and then depending on the results to give the B test. Ordering may be applied on part of the test as well (e.g. give first the X part and then the Y part of the test).
10) From a medical point of view, the need to keep records or the dependencies between screening data (Does an accurate diagnosis require to know the historical values as well?)

The metadata required for scales will be used in making a plan for statistical analysis in matchmakers and to prepare some visual layouts for medical reporting interface design.

Value Dependencies and Types of Graphs

The last requirement form the previous list (No. 10) should be explained in some more details before proceeding to visual layouts design. It is highly possible that there are

dependencies between scale results and other arithmetic values of medical interest. The main question here is: do we need to look at previous or other measurements in order to make sense of the results? Dependencies for screening data are very important for medical reporting and we care about the interface design for social and medical professionals. According to the reported dependencies, we can define the following forms of organizing and presenting the information:

- for **self-dependencies** (one value of the scale depends on previous values of the same scale), we need to present time series of measures to doctors. No other graph type can create the same value;

- for **stand-alone** measures we only need to present current status (e.g. line bars);

- for **groups of scale measures** we may need to use a 'spider-graph' (variables which can be grouped together).

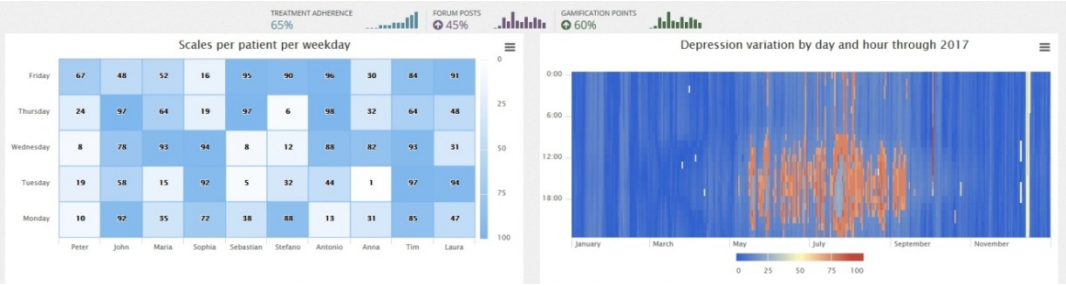
Medical Reporting

The Medical Reporting Service (MRS) is designed for reporting to the medical professionals the status of the monitored users regarding:

- The Treatment Adherence progress
- Scales Results per scale variable
- Expected results of selected variables of high medical value (like performance in the interactive interventions)
- Additional information like the performance in gamification

Error! Reference source not found. is an example of the proposed visual analytics interface for medical reporting. It contains three main areas: 1. the scales per user (upper-left), 2. The scales resulting heatmap (upper-right) and 3. the time series of the variable under study. The Depression scale is considered in this example. It is expected that a selector will be available for the medical professional to choose a scale from the list of the available scales. The **treatment adherence** is included in the list of the available scales.

Figure 6. Screenshot from a demo medical reporting template



The scales per user per weekday are a useful **table chart** that can give an overview of the scale results per test-taker. The numerical descriptor (arithmetic scale results) may appear in boxes, but the colour of the box indicates how the recorded results are compared to the expected results. The higher the colour value, the higher the score result.

Time series is a graph presenting series of data points indexed in time order. All scale results will be stored in the C-MMD database along with their timestamps at the time of the test. Based on the time information, the time series of high interest medical variables will be drawn as seen in the lower part of the *Figure 6* (dummy data example). The pink zone in the middle represents the zone of the expected or normal values. All values that lie outside this zone can be highlighted for professionals' interpretation. Additional interaction requirements for time series are:

1. choose a partial of the depicted time zone by using the pointing device selector

2. draw values over moving cursor (

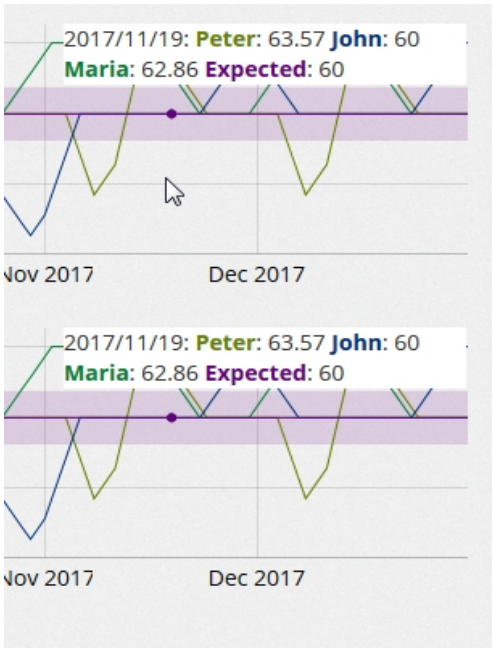
)

3. double click (or right click) to return to the normal view of the time series

4. Synchronize multiple time series on user's demand (like on the variable A & B of the *Figure 6* example)

For all charts, give users the option to print, download a screenshot of any of the presented charts, or download a pdf file (print as pdf) for reference and future use in reports. Those options may be accessed through short interactive menus next to each graph.

Figure 7. Screenshot from a demo social reporting template



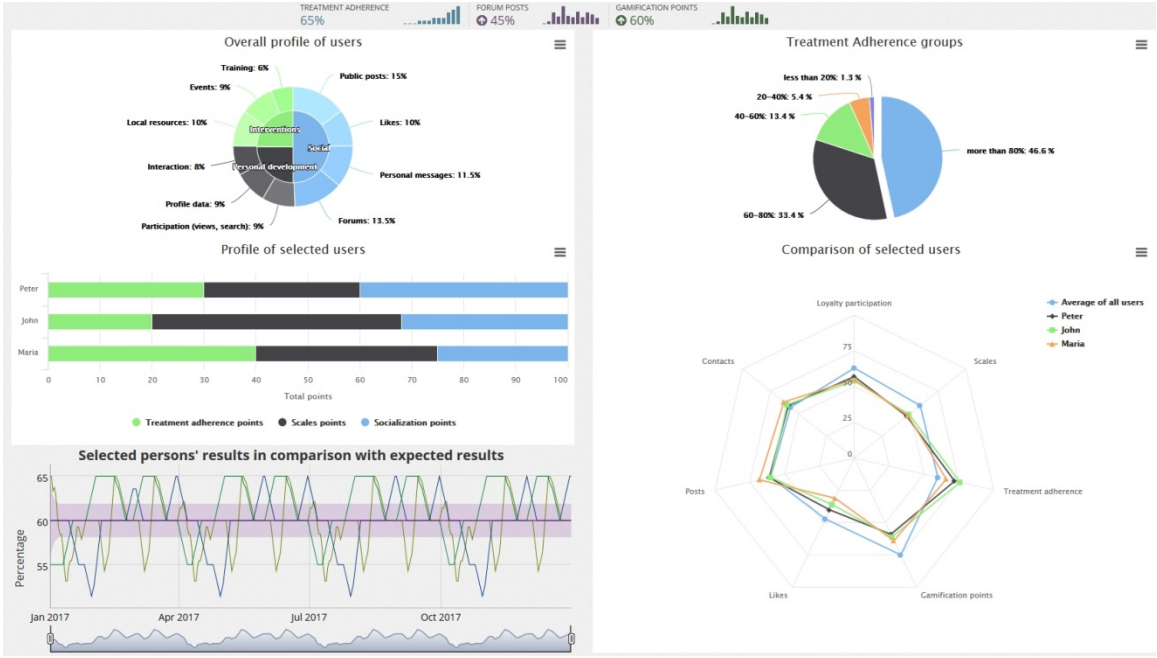
5.2 The Social Reporting Services of C-MMD SR

The **Social Reporting Service (SRS)** is designed for reporting to the social professionals the status of the monitored users regarding:

- The current social status and the progress in social interaction performed in the C-MMD platform
- Scales Results per scale variable related to the social status (social scales)
- Expected results of selected variables of high social value (e.g. data collected by in-house visits)
- Additional information like the performance in gamification

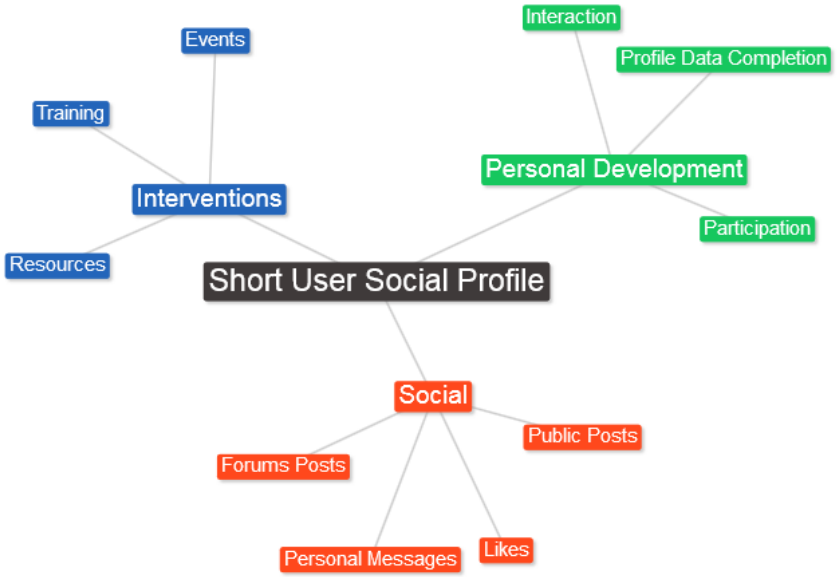
is a proposed visual analytics interface for medical reporting. It contains five main areas: 1. Overall user-profile (upper-left of **Error! Reference source not found.**), 2. Short social profile of selected users (middle-left part of **Error! Reference source not found.**), 3. The time series of the variable under study (lower-left part of Figure 8), 4. Treatment adherence status of all users under study (upper-right part of **Error! Reference source not found.**) and 10. Comparison of the social interaction of selected users (lower-right part of **Error! Reference source not found.**).

Figure 8. Screenshot from a demo social reporting template



The **short social profile** presents in a ring-diagram the current status of all interventions undertaken by a user or a group of users, their social activity and their personal development. Those three areas define the data model of the short social reporting service as presented in the mind-map of *Figure 9*.

Figure 9. Mind-map of the data model behind the short social reporting service



The **Stacked Bars** (middle-left part of **Error! Reference source not found.**) can give an overview on how specific users have gained their points. Assuming a standardized point system to reward user's activity in the platform, we may define three kinds of point sources: Treatment adherence, scales and socialization. This visual element is important to give the percentage of social activity over all other activities performed in the platform per user. In addition, social professionals can compare user's records in order to conclude on their relational personal development progress (e.g. Peter has gained more points by socialization activities in comparison to others).

Last, but not least, the **spider-graph** (or radar-chart) is a two-dimensional chart used to graphically displaying multivariate data of three or more quantitative variables. Those variables are represented on axes starting from the same point and developing radially to all directions. In the current example, seven (N = 7) variables have been supported, namely the participation (loyalty of the user), the number of contacts in the personal social network, the number of posts made in the platform, the number of likes, the gamification points, the current level of treatment adherence and the performance on requested scales (lower-right part of Figure 4).

5.3 The Personal Reporting Service

Although the clinical or social reporting services can present the current status and the progress made in a group of participants, there is still the need to have personal reports for specific individuals in order to identify/highlight changes in their health conditions and personal progress when following a treatment plan.

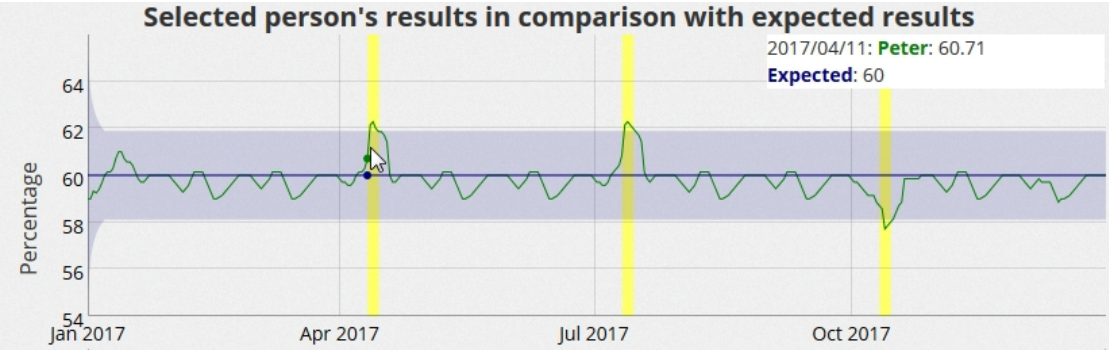
It is expected that a personal report would include series of timelines (each one related to social and medical variables) which will be based on recent clinical or social events and profile status. The comparison with the historical data (or baseline) will be possible through the use of visual interactive elements which will render both the historical data and the current user status (consider the example in Figure 10) in a personal reporting template with self service capabilities (Josefiok et al., 2015).

The personal reporting service will be accessed through the PLWD themselves or their caregivers and professionals who look after the PLWD. It is expected that the template design should include the following elements:

- Personal Information including the online user profile
- Names of caregivers and professionals who look after this person
- Symptoms and diagnosis information
- List of personalized interventions (either pharmacological or non-pharmacological)
- Monitoring data like plots of various medical and social variables (performance on scales, interactive interventions, etc.).
- List of recent alerts (if available)
- A summary of the personal social network (optional)

The personal reporting service presented above will be available online through the CMMD platform at any time, but will also be available in a printer-friendly format. Those personal reports may be used: 1. by doctors and social professionals during every day clinical and social processes, or could be stored in the local file system of the clinic (external to the CMMD) and 2. by PLWD and their caregivers in order to keep records of their own health and treatment management efforts. One example can be found on the Clinical Assessment template of the Pearson (http://www.pearsonclinical.com) in the address (last access 28 March, 2017): http://images.pearsonclinical.com/images/pa/pdfs/16pf5karson.pdf.

Figure 10. Example of risk detection using out-of-range data plot over historical data in the social, medical and/or personal reporting



In overall this reporting service should not be as complicated and difficult to use as market tools like SAP Crystal Reports (https://www.sap.com/product/analytics/crystal-reports.html) or EasyRiter (Dentrix, http://dentrixmarketplace.com/easyriter). It will be based on ready-made printer-friendly templates to export the available information of a user personal profile, scales and interaction history. To be noted that medical and social

professionals will be responsible for selecting which data and visual elements will be available to be included in the personal report template.

6 Recommendations and considerations

C-MMD SR is meant to be used in digital environments outside the platform, within the NHS systems. It is expected to provide additional information, which enriches the medical records of a user, and to be interoperable with the EHR. In this perspective, the added value of the C-MMD SR relies on the capability to consider the social dimension as part of a screening report, with specific and meaningful information that affect the choice of a treatment.

In this way, the C-MMD SR gives the opportunity to facilitate the implementation of a holistic, integrated and multidisciplinary approach to dementia, having the dyad and allowing the decision-making process at the point of care; therefore, it widens the range of information available in EHR, widening the sense and the possibility of the application of such a tool, allowing integrated care solutions and an integrated interpretation of the illness.

In order to fulfil this assumption, it is recommended to implement a SR providing not only meaningful, but also smart data. “Smart” means rich, in terms of organic and holistic view of the illness, and it means interoperable, in terms of language technically adopted for the report. Smart, also means safe: a security system to protect the data collected in the report is a recommended point in order to make the SR interoperable.

The amount of Smart Data produced by the C-MMD platform and collected in C-MMD SR might provide **insights in different fields**; in the clinical environments, they can be used to evaluate the efficacy of treatments, they can improve the quality (and quantity) of information about users’ reactions to care in order to improve the decision making process toward more personalised and more integrated care; in social environments, such data may be adopted to monitor users and better understand their care needs: the single case management can be facilitated by the provision of integrated information, combining the clinical data together with the trends of the mood, the feelings, the socialisation capabilities and the awareness about the disease and the need to deal with it.

It is important to clarify that it is a basic principle of C-MMD platform that the solution proposed for the SR will build **interoperability** on current national solutions of EHR as well as on national systems of integrated health and social care. This means that the access to, the exchange of and the processing on information of the SR must take into account the existing and under construction technological solutions within eHealth framework and must respect the laws and regulations as well at EU and national level; the interoperability, within the scope of C-MMD, is therefore the integration in the health and care systems. For the C-MMD SR, the recommendation to retain is about a minimum level of interoperability, aimed at achieving essential requirements with regard to semantic, technical, organisational and legal interoperability. In the framework of C-MMD platform, the interoperability is a key aspect for a double point of view: in terms of integration with EHRs systems in EU countries and in terms of multi-disciplinary purpose of the contents.

Also the research sphere can benefit from this smart data; it is, somehow a matter of **Big Data**. There is no lack of data for dementia research, but the need to exploit further this

data: the possibility to produce sharable data produced by a continuous monitoring may significantly improve the research in the field, and they can be exploited in different ways. To fully capture its potential, C-MMD SR may be considered as a tool to produce routinely big data which will allow a better understanding of the behaviours and environments of people living with dementia not only after diagnosis, but for prevention, early identification and diagnosis, or even to retrospectively analyse the years leading up to diagnosis.

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