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D3.2

e - CRF

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PU	Public, fully open, e.g. web	**X**
CO	Confidential, restricted under conditions set out in Partners Agreement	

HISTORY OF CHANGES

VERSION	SUBMISSION DATE	CHANGES
1.1	31/05/2023	
1.2	15/05/2024	Document included in new template. In Section 1.1 and in Section 4 is specified the meaning and the role of the work carried out by Activity 3 in the first two quarters of the Fit4MedRob Initiative, and its significance for the tasks of the other Activities of the Initiative.

TABLE OF CONTENTS

1 ABSTRACT AND OBJECTIVES

This document guides the design of e-CRFs that will collect data of the clinical studies of Fit4MedRob Initiative. The document:

- offers a general scheme that will guide the definition of the elements of the clinical protocols for each disease and scenario (section 2);
- offers direct links to the questionnaires that have been selected from the general list reported in Deliverable 3.1. (Table 1);
- explains how to obtain and validate an Italian version of the questionnaires that are not still available (section 4.2);
- offers guidelines for transforming a list of questions into an online questionnaire (eCRF) compatible with the most adopted platforms (e.g., RedCap) (section 4.3).

Related to each of the health conditions and diseases relevant in Fit4MedRob, the selection of the specific clinical questionnaires will allow us to update the present guidelines. Clinical questionnaires and clinical tests will be selected on the basis of the findings of the systematic review and recommendations of deliverable D3.1.

As emphasised in D3.1, in fact, the comparative analysis will be carried out through the design and conduct of clinical studies. The choice of the most appropriate measurement scales of the mentioned dimensions and of the most effective data collection tools to be used in clinical trials, is extremely important.

Therefore, the work done and the results presented in the current deliverable will be useful to the partners involved in the design of the clinical studies, as they will be able to start from the questionnaires and metrics highlighted in the next sections, and adapt them step by step to the very specificities of the objectives, the technologies involved, the setting chosen in the different studies.

2 GENERAL SCHEME

This section reports the general scheme of a multiuser eCRF able to link together: technology purpose, stakeholders involved, and dimensions for assessing the new solutions with respect to the standard of care.

The scheme identifies stakeholders as respondents to the questionnaires or responsible for filling the eCRFs.

In order to assess the impact of robotic solutions, questionnaires and issues related to the study arm (robotic solutions) and control group (standard of care) of clinical studies will be the same, with the exception of robotic-specific dimensions and the type of direct healthcare costs assessment: DRG i.e., reimbursement regimes for type of rehab (inpatient, outpatient), and a microcosting approach for assessing costs of robotics for inpatient, outpatient, and at home rehabilitation.

If not specified, the reported issues refer to questions for involved stakeholders in both the study arm and control group.

2.1 ROBOTIC TECHNOLOGY AS REHAB SOLUTION

2.1.1 Inpatient rehab

2.1.1.1 Final user/families

Effectiveness

- Tests (to be defined on the list available in D.3.1 for each disease).
- Clinical Questionnaires (to be defined on the list available in D.3.1 for each disease)
- PREMs & PROMs Questionnaires
    - Quality of life
        - Disease specific (one for each disease)
            - Stroke Impact Scale
            - Spinal Cord Injury QoL (SCI-QoL)
            - Multiple Sclerosis Impact Scale
            - Parkinson's Disease Rating Scales
        - Generic
            - EQ-5D
            - SF-36
        - Daily Living: Barthel Activities of Daily Living Index (BADLI)
        - Physical Activity Exercise Barrier Self-Efficacy (EBSE)
        - Depression Beck Depression Inventory –Fast Screen (BDI-FS)
        - Fatigue Severity Scale (FSS)
        - Anxiety
            - Hospital Anxiety and Depression Scale (HADS)
            - General Anxiety Disorder- 7 (GAD-7)
        - Pain (Generic): Numeric Pain Rating Scale (NPRS)

Costs

- **Direct non-health costs/ out-of-pocket costs:**
    - CoPaQ questionnaire
    - Leisure time spent by the principal caregiver (e.g., a relative, a partner) for assisting the final user
- **Indirect costs** (as respondent, indirect costs are usually part of societal costs, but patients and principal caregivers are usually reimbursed for working day lost because of disease)
    - End users
        - working days lost in the last month related to the disease/health condition (e.g., hospitalizations, visits, etc.)
        - daily salary
    - Principal caregiver
        - working days lost in the last month for assisting his/her relative
        - daily salary

Acceptability & Usability Questionnaires

- System Usability Scale questionnaire (SUS)

    - Usefulness, Satisfaction, and Ease of use Questionnaire (USE)
- ICT skills
- Acceptability/usability/easy of use
- Perceived complexity

Healthcare/professionals

Effectiveness

- Scores of the tests involving patients must be automatically or manually inserted by healthcare professionals in the eCRF.
- SREMs (Staff Reported Outcome) & SROMs (Staff Reported Experience)
    - Working related quality of life: WRQoL.

Acceptability & Usability Questionnaires

- ICT skills
- Acceptability/usability/easy of use
- Perceived complexity
- Willingness to use (study group)
- Willingness to recommend the use of the technology (study group)

Organizational issues

- Physiotherapists mental workload
- Physiotherapists physical workload

Hospital facilities

Acceptability/usability

- Ad hoc questionnaire on easy of use, utility, acceptability, usability
- Willingness to adopt (study group)
- Willingness to buy and cost threshold (study group)

Organizational Issues / Organizational KPIs

- Number of patients annually managed by the structure
- Number of sessions per patient
- Staff to patient ratio: number of patient managed contemporary in each rehab section
- Average length of hospital stay
- Patient wait time
- Bed turnover
- Bed occupancy rate
- Readmission rate
- Number of beds dedicated
- Set-up time
- Space requirements
- Training time/learning curve

Economic KPIs

- Average Cost per Discharge
- Reimbursement (DRG) (control group)
- Operating Cash Flow: cash reimbursement and revenues - operating expenses paid in cash
- AR Turnover: net credits/average account receivable
- Net Profit Margin: Net Income / Total reimbursement
- Reimbursement Time

Costs

- **Direct health costs**
  - Cost of the technology
    - Original price
    - Annual Maintenance costs
    - Life cycle
    - Cost of consumables per rehab session
    - Cost of energy per rehab session
  - Healthcare professional salary
  - Rehab session length

2.1.2 Outpatient rehab

The same issues of inpatient rehab.

2.1.3 At home rehab

The same questionnaires and issues of inpatient rehab. However:

- questionnaires for healthcare professionals only if they are involved;
- questionnaires on organizational issues of hospital facilities only if the at home rehabilitation is directly managed by the hospital facility;
- final users and families should answer to The OECD Model Survey on ICT Access and Usage by Households and Individuals, Module C.

2.2 ROBOTIC TECHNOLOGY AS SUPPORTING SOLUTION

2.2.1 Final user/families

Effectiveness

- Tests (to be defined on the list available in D.3.1 for each disease).
- Clinical Questionnaires (to be defined on the list available in D.3.1 for each disease)
- PREMs & PROMs Questionnaires
  - Quality of life
    - Disease specific

- Quebec user evaluation of satisfaction with assistive technology (QUEST)
- Psychological Impact of Assistive Devices Scale (PIADS)

- Generic

The same of the inpatient rehab scenario

Acceptability & Usability Questionnaires

The same of the rehab scenario

Costs

- **Direct health costs**
  - Therapies, daily dosage and duration (as respondent only)
  - Hospitalizations (as respondent only)
    - Number and type of hospitalization
    - For each hospitalization, hospitalization length
- **Direct non-health costs/ out-of-pocket costs:**
  - CoPaQ questionnaire
  - Leisure time spent by the principal caregiver (e.g., a relative, a partner) for assisting the final user
  - Cost of the technology (if not reimbursed)
- **Indirect costs** (as respondent, indirect costs are usually part of societal costs, but patients and principal caregivers are usually reimbursed for working day lost because of disease)
  - End users
    - working days lost in the last month related to the health condition (e.g., hospitalizations, visits, etc.)
    - daily salary
  - Principal caregiver
    - working days lost in the last month for assisting his/her relative
    - daily salary

Healthcare professionals

(as personnel involved in the experimentation phase -no impact has to be assessed)

- Scores of the tests involving patients must be automatically or manually inserted by healthcare professionals in the eCRF.

Healthcare system

Acceptability/usability

- Willingness to adopt (study group)
- Willingness to buy and cost threshold (study group)

Ad ad hoc questionnaire.

Costs

- **Direct health costs**
  - Hospitalizations: DRG (for each type of hospitalization)
  - Technology costs
    - Original price
    - Annual Maintenance costs
    - Life cycle
    - Monthly number and costs of consumables
    - Daily use (hours)

3 CRITERIA OF SELECTION OF QUESTIONNAIRES

The document presents an exhaustive compilation of the principal criteria that were scrutinized to determine the paramount questionnaires related to the field of robotic rehabilitation technology and its potential impact on individuals' lives.

The main criteria considered were, in hierarchical order:

1. Validation
2. Number of issues
3. Frequency of use in the literature
4. Italian translation (if any)

3.1 QUESTIONNAIRES SELECTED

This chapter constitutes the essence of the present deliverable as it contains the hyperlinks to the questionnaires that have been selected for each topic. Each hyperlink provides access to all the questions that comprise the final electronic Case Report Form (eCRF).

In order to identify clinical outcomes related to the field of robotic rehabilitation technology and for each disease reported within the Fit4MedRob Initiative, a meeting among clinicians is required. The meeting aims to identify the assessment scales to be included in the final electronic Case Report Form (eCRF).

Table 1. Selected questionnaires and the relative link (end users and patients as respondents)

Topic	Questionnaire	Link	Italian version (direct link or link to the website with the instructions)
General Aspects	Digital Skills Questionnaire	vINCI-Call-2017-DIGITAL-SKILLS-QUESTIONNAIRE-END-USERS.pdf	to be translated, see section 4.2

	Perception of the complexity of the problem	Perception of the complexity of the problem.pdf	to be translated, see section 4.2
	Working related Quality of Life	WRQoL individual booklet Dec2013.pdf	to be translated, see section 4.2
	Technology Adoption Survey	Technology Adoption Survey.pdf	to be translated, see section 4.2
Clinical Aspects	They will be defined on the basis of the consensus among clinicians on the most relevant dimensions for assessing the effectiveness of robotic solutions. The number, type of clinical questionnaires will be defined in each clinical study considering the review reported in deliverable D.3.1 For an overview of the existing metrics see Deliverable D3.1, sections 3.2.1 available at: https://docs.google.com/document/d/1SAsiXmjk5t99EtXZRubOwO5WNd-3nZqL/edit#heading=h.7ntyi1wl7lq2		
PROMs/PREMs	QoL Generic	European (5D) Quality of Life Scale (EQ-5D5L)	http://centrostudi.anmco.it/csweb/uploads/12-Questionario_EQ-5D-5L.pdf (authorization must be obtained following instruction at: https://euroqol.org/eq-5d-instruments/all-eq-5d-ver)
		36-Items Short Form (SF-36)	https://www.fisioscience.it/wp-content/uploads/2022/02/sf_-_36.pdf No authorization is requested as indicated in:

			https://www.rand.org/health-care/surveys_tools/mos/36-item-short-form/terms.html
	QoL Specific	Stroke Impact Scale	https://www.nurse24.it/images/allegati/NIHSS-Versione-Italiana.pdf
		Spinal Co\oL (SCI-QoL)	to be translated, see section 4.2
		Multiple Sclerosis Impact Scale	to be translated, see section 4.2
		Parkinson's Disease Rating Scales (MDS-URPDS) https://www.movementdisorders.org/MDS-Files1/PDFs/Rating-Scales/MDS-UPDRS_English_FINAL.pdf	https://www.movementdisorders.org/MDS-Files1/PDFs/MDS-UPDRS-Rating-Scales/MDS-UPDRS_Italian_Official_Translation_FINAL.pdf
	Daily Living	Barthel Activities of Daily Living Index (BADLI)	https://www.fisioscience.it/scale-valutazioni/barthel-index/
	Physical Activity	Exercise Barrier Self-Efficacy (EBSE)	to be translated, see section 4.2
	Depression	Beck Depression Inventory – Fast Screen (BDI-FS)	https://www.dors.it/public/ar28/Beck%20Inventory%20Scale.pdf

	Fatigue	Fatigue Severity Scale (FSS)	https://www.sleepontario.com/docs/scales/FSS/FSS_Italian.pdf
	Anxiety	Hospital Anxiety and Depression Scale (HADS)	https://www.fondazionelimpe.it/web/image/72293/hospital-anxiety-and-depression-scale-italiano.pdf
		General Anxiety Disorder- 7 (GAD-7)	https://psichiatra-a-milano.it/wp-content/uploads/2012/12/Test_di_valutazione_per_i_sintomi_del_GAD_o_disturbo_dAnsia_Generalizzato-psichiatra-a-milano.it_.pdf
	Pain (G)	Numeric Pain Rating Scale (NPRS)	https://www.fisioscience.it/scale-valutazioni/scala-nrs/
Economic Aspects			
Direct health costs	Ad-hoc questionnaires	Direct health costs.pdf	to be translated, see section 4.2
Direct non-health costs	CoPaq	Cost_issues (2).pdf	to be translated, see section 4.2
Indirect costs	Ad-hoc questionnaires	Indirect non_health costs.pdf	to be translated, see section 4.2

Accessibility/ Usability Aspects	Quebec user evaluation of satisfaction with assistive technology (QUEST)	Quebec User Evaluation of Satisfaction with assistive Technology.pdf	https://portale.siva.it/it-IT/databases/libraries/detail/id-95
	Psychological Impact of Assistive Devices Scale (PIADS)	PIADS_MANUAL.pdf	https://portale.siva.it/files/doc/library/a90_1_Strumento_PIADS_Questionario_Italiano.pdf
	System Usability Scale questionnaire (SUS)	System Usability Scale questionnaire (SUS).pdf	https://www.cognitivelab.it/wp-content/uploads/2011/07/SUS-scheda.pdf
	ICT Model Survey Access Usage Households Individuals	ICT-Model-Survey-Access-Usage-Households-Individuals.pdf	to be translated, see section 4.2
Organizational factors	Usefulness, Satisfaction, and Ease of use Questionnaire (USE)	USE Questionnaire_ Usefulness, Satisfaction, and Ease of use.pdf	to be translated, see section 4.2

3.2 STAKEHOLDER'S PROFILE

Personal profiling is related to a few questions that are summarized in the below table.

Table 2. Variables adopted for profiling personal characteristics.

Dimensions	**Principal Stakeholders involvement in feeling the questionnaire**		
	Patients	Parents/families	Healthcare operators

Name and Surname	x	x	x
Age	x	x	x
Civital status	x	x	
Education and Job	x	x	x
How long have you been working as a healthcare professional? (years)			x
How long have you been working as a healthcare professional in your current role? (years)			x
In the last month, how many patients did you visit? (N)			x

4 GUIDELINES FOR DESIGNING ECRF

This chapter serves as a concise guide on how to upload the primary questionnaires selected within the most commonly used software programs for survey creation. In this manner, a comprehensive guide will be completed on how to effectively frame questions pertaining to emerging technologies, and how to construct an actual survey instrument to efficiently collect data.

4.1 HOW TO OBTAIN QUESTIONNAIRES FROM THEIR OWNERS

Some questionnaires are not open source. However, they are usually for free if you demonstrate that their use is not for a commercial purpose. It is, for instance, the case of EQ-5D.

To obtain this kind of questionnaires, you have to:

- register on the related website;
- fill the few questions asking the name and type of study that requires the questionnaire;
- specify that the use is not for a commercial use;
- select the types of available questionnaires (e.g., different questionnaires related to age of the respondents and in the Italian version). Usually, there is the possibility to directly select the file extension related to RedCap or other commonly adopted platforms. If it is the case, you can ignore section 4.3 of the present guide;
- wait a few hours or days to obtain the authorization to download the selected questionnaires.

4.2 How to obtain the Italian versions of the questionnaires

For many questionnaires there is the Italian version. In the case an Italian version of the questionnaire is not available, there are some opposite challenges:

1. If questionnaires are very easy and respondents have sufficient skills and they accept, the original form can be administered;
2. If respondents do not accept, one has to select another questionnaire or to translate in Italian from the original version.
    a. The questionnaire is open source: start the translation procedure.
    b. If the questionnaire's owner does not allow the translation we should select another questionnaire.
    c. If the questionnaire's owner accepts, we can start the translation.

In any case validating an original questionnaire in a specific language needs the following steps (4.2.1, 4.2.2, 4.2.3).

4.2.1 Forward translation

The initial translation from the original language to Italian:

- two independent translators (at least), preferably bilingual. One translator should be aware of the concepts of the questionnaire and one translator should be naive. Discrepancies between the translators can be discussed and resolved between the original translators, or with the addition of an unbiased, bilingual translator.

4.2.2 Backward translation

From Italian to English:

- the initial translation should be independently back-translated to ensure the accuracy of the translation.

4.2.3 Validation

4.2.3.1 Top-down validation

The obtained version of the questionnaire will be finalized by a group of experts involving:

- experts familiar with the construct of interest,
- a methodologist,
- the forward and backward translators;
- developers of the original questionnaires.

4.2.3.2 Bottom-up validation

The questionnaire is administered to a subset of respondents that are asked to elaborate what they thought each questionnaire item and their corresponding response meant.

The above steps were mandatory for validating a translation (Tsang et al. 2017). In the era of high quality AI-based translators we believe that steps 1- 2 are not necessary. However an expert and bottom-up validation is mandatory.

4.3 Compatible files

If the questionnaires are not in the format of the adopted platform, to create an eCRF you have to start from an excel file (format xlsx). This format is compatible with the most adopted platforms for online survey (Microsoft Form, Google Form, RedCap).

Therefore, if a questionnaire is available in PDF, you need a PDF-xlsx converter. From the obtained file, please select only questions and create a new docx that will be imported.

4.3.1 Procedure

- Open the Excel file containing the questions you want to use in your questionnaire.
- Review the questions and make any necessary edits to ensure they are properly formatted and fit the needs of the study.
- Save the Excel file as a CSV (Comma Separated Values) file.
- **For Microsoft Forms**:
    - a. Go to the Microsoft Forms website and sign in using your Microsoft account.
    - b. Click "New Form" and choose "Import questions" from the "Add question" dropdown menu.
    - c. Select "From a CSV file" and upload the CSV file containing your questions.
    - d. Microsoft Forms will automatically create a question for each column in the CSV file. Review and edit the questions as necessary.
- **For Google Forms**:
    - a. Go to the Google Forms website and sign in using your Google account.
    - b. Click "Blank" to create a new form.
    - c. Click the "Import questions" icon in the toolbar.
    - d. Select "From a Google Sheets spreadsheet" and choose the CSV file containing your questions.
    - e. Google Forms will automatically create a question for each column in the CSV file.
    - f. Review and edit the questions as necessary.
- **For REDCap:**
    - a. Go to the REDCap website and sign in using your REDCap account.
    - b. Select the project you want to add the questionnaire to and click "Design" and then "Online Designer" from the project menu.
    - c. Click "Import Survey" and choose the CSV file containing your questions.
    - d. REDCap will automatically create a question for each column in the CSV file.
    - e. Review and edit the questions as necessary.
- Save and publish the questionnaire in the desired format for your study.

REFERENCES

Tsang S, Royse CF, Terkawi AS. Guidelines for developing, translating, and validating a questionnaire in perioperative and pain medicine. Saudi J Anaesth. 2017 May;11(Suppl 1):S80-S89. doi: 10.4103/sja.SJA_203_17. PMID: 28616007; PMCID: PMC5463570.