

### 3.3.1. Reports from implementation of testing phase in territorial Health Living Labs (real-world setting)



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## GUIDELINE

### KEY DEFINITIONS:

A **prototype** can be perceived as something being built to represent a product or experience before the actual artefact is completed.<sup>1</sup>

**Pilot test** should provide insights into anything that might be missing in the innovation, so this can be adjusted before the complete roll-out to a larger group of test users.<sup>2</sup>

**Real-world health care setting** place/location existing or occurring in reality, e.g. hospitals, clinics and pharmacies across diverse geographies, enabling to obtain by researchers real-world evidence (RWE) based on real-world data (RWD)

**Real-world evidence (RWE)** is evidence about the use, safety and effectiveness of a medical product, technology or drug that is based on or derived from analysis of data generated in a real-world health care setting.<sup>3</sup>

**Real-world data (RWD)** includes information about the health of individuals or the delivery and/or outcomes of health care that is collected outside of traditional clinical trials and thus reflects results within the context of the particular health care system.<sup>4</sup>

**Implementation** is defined as a specified set of activities designed to put into practice an activity or program.<sup>5</sup>

Within innovation research and living lab projects, a crucial component is to test an innovation in a real-life context with potential end users. Such a field test can validate assumptions by combining insights on behaviour and attitudes towards the innovation. This allows for iterative tailoring of the innovation to the needs and wants of the potential end users. Moreover, relevant insights can be gathered to stop or rescope the innovation project before big investments are made. Although studies indicate that testing innovations (or prototypes) in real-life contexts improves the innovation process, there is no specific framework on how to conduct a field test for an innovation. Therefore, for the needs of the solutions proposed in the project and after reviewing the literature on the subject, the following path for implementation of testing phase in real-word setting was proposed:

1. Finish the recruitment process of 20 patients with their relatives. The recruited participants should be those who are confronted with the solution (**end of September 2024**).
2. Prepare all the necessary protocols, written consents etc. based on the national regulations or internal regulations of the institution which should be filled in and signed by the participants.

<sup>1</sup> Sanders, E. B.-N., & Stappers, P. J. 2012. Convivial Toolbox: Generative Research for the Front End of Design. Amsterdam: BIS.

<sup>2</sup> Coorevits, L., Georges, A., & Schuurman, D. 2018. A Framework for Field Testing in Living Lab Innovation Projects. Technology Innovation Management Review, 8(12): 40-50.

<sup>3</sup> Chodankar D. Introduction to real-world evidence studies. Perspect Clin Res. 2021 Jul-Sep;12(3):171-174. doi: 10.4103/picr.picr\_62\_21. Epub 2021 Jul 7.

<sup>4</sup> As above

<sup>5</sup> Implementation Stages | NIRN". nirn.fpg.unc.edu. National Implementation Research Network. Archived from the original on 2022-05-23. Retrieved 2022-01-26.



3. Before the first confrontation the users with the solution, there should be a pre-test phase using PREMs and PROMs specifically adapted to the evaluated solution. Use also some other forms of evaluation if possible, e.g. measurement devices.
  4. Store all the data from pre-test phase: both forms, electronically or in paper is possible.
  5. Users react to and interact with the new solution.
  6. At the end of the testing, post-test phase using the same PREMs and PROMs should be provided to gain quantitative insights.
  7. Store all the data from post-test phase: both forms, electronically or in paper is possible.
  8. Analyse/Compare the results obtained from pre- and post-tests.
  9. Summarize the results with reporting the final feedback for the prototype improvements.
- HCOs with Teams play a key role in that phase with the support of KPs with their expertise.
- The challenges and progress will be discussed with other piloting regions during the monthly calls facilitated by WP T3 leader on a transnational level.

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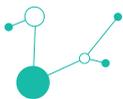
1. **Did you need to prepare any additional protocols, written consents etc. except PREMs and PROMs questionnaires? If YES, describe them and explain why it was necessary.**

In addition to the standardised PREMs (Patient-Reported Experience Measures) and PROMs (Patient-Reported Outcome Measures) questionnaires, additional protocols and informed consent forms were required. These were prepared in accordance with the internal regulations of the University Hospital Carl Gustav Carus Dresden (UKD) and Carus Consilium Sachsen GmbH (CCS) and signed by all participants.

The additional documents required included

- Informed consent forms: These ensured that the participants were fully informed about the procedure, objectives and conditions of the test phase and gave their voluntary consent.
- Data protection declarations: These informed the participants about the processing of their personal data, in particular about the measures for pseudonymisation, and about their rights under the General Data Protection Regulation (GDPR).

An ethics vote was not required in this project phase because no invasive or otherwise ethically critical procedures were performed.



In addition to the PREMs and PROMs questionnaires, further evaluation questionnaires were developed and used in collaboration with the developers of the ActiveTEP app. These additional questionnaires were used to collect more detailed information on specific aspects of app use, user-friendliness and patient satisfaction.

## 2. How did you store the data and how did you secure them?

The data collected during the test phase were stored both electronically and in paper form and processed in compliance with the applicable data protection guidelines.

### a) Electronic storage:

All digital data was stored on the secure servers of the University Hospital Carl Gustav Carus Dresden, which meets the current IT security standards. Access to the electronic data was restricted to authorised employees only and was protected by personalised access data. All personal data was stored pseudonymously so that it could not be directly assigned to individual participants.

To avoid data loss, regular backups were performed and stored on separate, also secured servers.

### b) Storage in paper form:

Written consent forms and completed questionnaires were stored in lockable filing cabinets that were only accessible to authorised personnel.

The retention period was determined in accordance with the internal data protection guidelines; after this period has expired, the documents are destroyed in a manner that complies with data protection requirements.

### c) Additional security measures:

The processing and storage of the data was carried out strictly in accordance with the requirements of the GDPR and the internal data protection guidelines of the University Hospital. All employees involved were trained in data protection and data security and were bound to confidentiality.

Firewalls, regular security updates and encryption technologies were used to secure the digital data.

## RESULTS

Present the results from pre- and post-phase test phase. Also, tables and graphs are possible to be used here.

### Results from Pre- and Post-Test Phases

#### *Pre-Test Phase*

The pre-test phase was conducted with a group of eight participants, comprising two women and six men, aged between 64 and 84 years. A significant feature of this group was their relatively high familiarity with digital technologies. Most participants expressed confidence in using devices such as computers, smartphones, tablets, and smart TVs. Additionally, 60% of participants had



prior experience with digital health applications, suggesting a certain degree of understanding and openness to digital solutions.

The main focus of the survey was to explore participants' expectations and requirements for digital health applications. One of the most notable findings was that all eight participants highlighted the importance of an easy installation process across multiple devices. This indicates that the first step of downloading and setting up the application plays a crucial role in fostering user acceptance. Five of the eight participants also emphasised the significance of a simple and intuitive registration process. This suggests that ease of registration is an important factor for older users, allowing them to quickly and easily begin using the application.

Additionally, clarity of design and readability were identified as key requirements by five participants. This indicates the necessity for a user-friendly interface with large, legible fonts and a clear structure to ensure accessibility for older users. Regarding the long-term use of digital applications, the participants also indicated that an application must be easy to use on an ongoing basis. Six of the eight participants expressed that they would only continue using an application over time if it was simple to operate and offered a clear benefit to their health and well-being. One participant also suggested that a rewards programme could serve as an additional incentive to encourage continued use.

In summary, the findings from the pre-test phase show that the user-friendliness of a digital health application is paramount. An easy installation process, a straightforward registration procedure, and clear design with a large, legible font are essential to ensure that older users find the application accessible and appealing. Additionally, the application must provide a tangible benefit, particularly in terms of health, in order to motivate users to continue using it in the long term.

#### *Post-Test Phase*

The post-test phase involved 23 participants, aged between 33 and 85 years. The group consisted of eleven women and twelve men. When asked about the frequency of using digital applications (such as apps, websites, etc.), 17 participants reported frequent use, while one participant stated they used digital applications once a week, and one participant reported never using digital applications.

The survey further explored participants' expectations and needs for digital applications. The most commonly mentioned requirements were the ease of installation across devices (17 mentions), followed by a simple registration process (14 mentions), easy, intuitive, and self-explanatory handling (14 mentions), as well as clear design (17 mentions) and a well-structured layout (14 mentions). Less frequently, but still noteworthy, were the importance of a readable font size (12 mentions) and the use of clear visual language, particularly in the form of icons (6 mentions).

When participants were asked what would make it easier for them to use digital solutions regularly over the long term, 19 participants highlighted the importance of easy usability. Thirteen



participants felt that the personal benefit of the application was also crucial, while six participants expressed a desire for in-app support and assistance. Three participants mentioned that a rewards programme would be a useful addition.

The results regarding the ActiveTEP feature for hip replacement patients showed overwhelming approval. 94% of respondents believe that the app could provide valuable assistance in preparing for a hip replacement surgery. This high approval suggests that participants appreciate the opportunity to engage with the application before surgery in order to better understand the process and prepare. The approval for post-surgery support was even higher, with 96% of participants considering it a valuable tool for rehabilitation. This indicates that the majority of participants saw the app as a helpful resource during recovery.

In terms of the app's design and layout, all 23 participants indicated that they found the design visually appealing. This positive feedback suggests that the design was well received, and the app was perceived as aesthetically pleasing, which is crucial for long-term engagement. Regarding the clarity of the app's structure, 18 participants confirmed that the app was easy to navigate, while only one participant felt it could be improved.

Furthermore, when participants were asked if they would consider using the ActiveTEP app if it were recommended by their healthcare provider, all 23 participants responded positively, indicating that the app was perceived as valuable and there was considerable interest in using it under appropriate circumstances.

Regarding the conditions under which participants would be willing to use the app in the future, several factors were highlighted. The majority (17 participants) stated that they would be more likely to use the app if it were recommended by medical professionals, underlining the importance of professional endorsement in driving user acceptance. Eight participants indicated they would consider using the app if it were covered by their health insurance, suggesting that financial accessibility plays a significant role in the decision to use digital health tools. Five participants mentioned that they would need an introductory session or tutorial on how to use the app. This indicates that clear guidance on the app's functionality is essential to ensure users feel comfortable using it. Finally, 12 participants emphasised the importance of the app clearly demonstrating its benefits in terms of treatment outcomes, which would influence their decision to use it regularly.



Comparison of Pre- and Post-Test Phases

*General Usability:*

Requirement / Expectation	Pre-Test Phase (8 Participants)	Post-Test Phase (23 Participants)
Easy installation	100%	89%
Simple registration process	62,5%	73,7%
Intuitive usability	62,5%	73,7%
Clear design / readability	62,5%	89%
Personal benefit	75%	68,4%
Rewards program	12,5%	15,8%

*Relevance for patients:*

Question	Pre-Test Phase (8 Participants)	Post-Test Phase (23 Participants)
Preparation for hip surgery helpful	100%	94%
Post-surgery support helpful	100%	96%
App design appealing	87,5%	100%
App clear and well-structured	100%	94,7%
Would use app if indicated	100%	100%

*General handling:*

Requirement / Expectation	Pre-Test Phase (8 Participants)	Post-Test Phase (23 Participants)
Easy installation	100%	89%
Simple registration process	62,5%	73,7%
Intuitive usability	62,5%	73,7%
Clear design / readability	62,5%	89%
Readable font size	62,5%	63,2%
Clear visual language / icons	12,5%	31,6%
Well-structured layout	62,5%	73,7%

*Conditions for Future Use of the ActiveTEP App:*

Condition	Post-Test Phase (23 Participants)
Recommendation by healthcare professional	68,4%
Coverage by health insurance	42,1%
Introductory session on how to use the app	26,3%
Recommendation to friends / family	15,8%
Clear display of benefits for treatment outcome	63,2%



The results from both the pre- and post-test phases demonstrate a high level of consistency in participants' expectations for digital health applications. The importance of easy usability, clear design, and personal benefits was consistently highlighted across both phases. In particular, participants in both phases emphasised the need for a straightforward installation process, a simple registration procedure, and an intuitive, easy-to-navigate interface.

The "Active TEP" app received overwhelmingly positive feedback, with the vast majority of participants expressing interest in using the app if it were recommended by their healthcare providers and if it provided clear benefits related to treatment outcomes. These findings suggest that professional endorsement and demonstrated benefits are crucial factors for increasing the likelihood of long-term use.

Ultimately, both phases emphasise the importance of user-friendly design and clear communication of the app's benefits in encouraging the adoption and sustained use of digital health applications among older adults, particularly in the context of surgical preparation and rehabilitation.

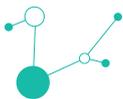
**If you were able to notice any additional opinions/comments about the solution except the results from PREMs and PROMs, describe them here.**

In addition to the Patient-Reported Experience Measures (PREMs) and Patient-Reported Outcome Measures (PROMs) results, several additional opinions and comments were provided by participants that provide deeper insight into the solution's perceived strengths and areas for improvement. One important aspect mentioned by several participants was the need for a more personalised experience within the application. Features such as customisable font sizes, custom notification settings, and content tailored to individual recovery progress were suggested as valuable additions to improve usability and engagement.

Additionally, some participants expressed a desire for additional support features within the app, such as a built-in chatbot or direct messaging functionality with a healthcare professional. These features would help users address uncertainties about their rehabilitation process and receive timely support when needed.

Although most participants were familiar with digital technologies in both the pre- and post-test phases, some older users expressed concerns about potential barriers for people with less digital knowledge. A thorough introduction to the application could help here.

Motivation was also identified as a crucial factor for long-term use of the application. While some participants suggested a reward or bonus programme as an incentive, others emphasised the importance of motivational elements such as progress tracking, goal-setting features and positive reinforcement messages to encourage continued use.



## CONCLUSIONS:

**Summarise the results with their practical application.**

The results of the pre- and post-test phase underscore both the great potential and the exciting possibilities for further developing the ActiveTEP app in patient care. The overall positive response shows that the app can already make a valuable contribution to supporting recovery, while targeted optimisations can further improve the user experience.

A particularly important aspect is user-friendliness, which plays a key role in long-term acceptance. The majority of participants appreciated the clearly structured instructions and informative content. At the same time, there are opportunities to make the app even more intuitive to use, especially for users with less digital experience. Interactive onboarding processes, clear video tutorials or in-app instructions could ensure that all patients can use the app's features effortlessly and to their full extent.

Self-monitoring and activity tracking also offer great potential for optimising the rehabilitation process. While some participants did not initially fully recognise the direct benefits of these features, a more personalised design - for example, through goal-setting tools, personalised progress feedback or the involvement of medical professionals - could make the added value even more tangible for patients.

In addition, it has been shown that flexible pricing or possible reimbursement models by health insurance companies could further increase accessibility. This would enable even more patients to take advantage of the app for their recovery.

Last but not least, the desire for even more customisation of the app was expressed. Although the design has already been very well received, advanced personalisation options - such as customisable content, variable difficulty levels in the training modules or personalised reminders - could help to tailor the app even better to the individual needs of users.

In addition to optimising the existing functions, the developers are already considering expanding the scope of the application. While the app is currently aimed at patients who have had hip replacement surgery, it could be made available to other patient groups in the future, such as people who have had knee replacement surgery. By adapting the content to different medical conditions, ActiveTEP could support even more patients on their road to recovery in the future.