IDEA-FAST

Identifying Digital Endpoints to Assess FAtigue, Sleep and acTivities in daily living in Neurodegenerative disorders and Immune-mediated inflammatory diseases.

Grant Agreement No. 853981

WP3 – Digital Devices and Technology

D3.1 - Device Selection Criteria and Documents / Processes for Gathering Evidence

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Other contributors	All members of WP3, as well as collaborators from the TFTI and WP4.

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1 Abstract

This report presents the device selection process and materials for the IDEA-FAST project. The project aims to identify digital endpoints to assess fatigue, sleep and activities of daily living in neurodegenerative disorders and immune-mediated inflammatory diseases. The project includes a feasibility study that will serve to assess the possibility of mapping data collected through a range of different sensor devices and behaviour tracking applications to several clinical concepts of interest. The feasibility study (FS) will also assess the acceptability of the devices in order to inform a further selection of devices towards a large-scale clinical validation study.

This report provides information on the device selection criteria, processes and documents produced in the pre-FS phase of the project, which also forms the first deliverable that is part of work-package (WP) 3 *Devices and Technology* (deliverable D3.1 [project internal numbering] or 8 [in the project officer count]: Device selection criteria and documents / processes for gathering evidence). This includes the rationale and development report for device selection criteria as well as evidence collection processes and materials (as designed for and employed in pre-FS phase, together with - where applicable - adjustments in preparation for the FS).

2 Introduction

An ambitious clinical validation study (CVS) will form the central practical element of the IDEA-FAST project. In order to inform the most promising mappings between sensor data streams and the clinical concepts of interest defined in the project, as well as to inform the best possible selection of specific devices and applications to produce the data streams, a feasibility study (FS) is required. However, as the feasibility study itself already forms and ambitious endeavour, the project requires multiple device selection phases. In general terms: 1) a pre-FS device selection and 2) a pre-CVS device selection.

This report will provide a general background of the project and work-package (WP) 3 (Devices and Technology) as the WP in which these activities are primarily rooted. The report then summarises the general device selection criteria, processes and documents produced for the pre-FS phase of the project, which will be made available as the first formal delivery of WP 3 “Devices and Technology”: Deliverable 3.1 / 8: Device Selection Criteria and Documents / Processes for Gathering Evidence.

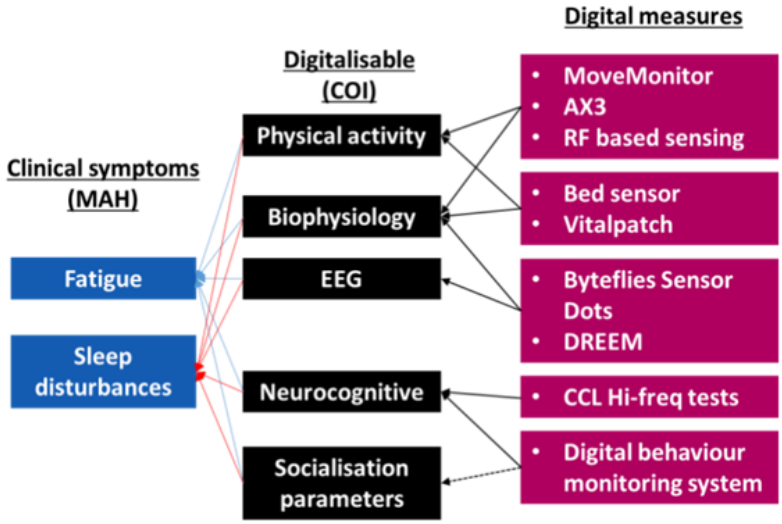

Figure 1: Overview of the targeted clinical symptoms and related digitalisable concepts of interest, together with candidate technologies for producing informing sensor or behavioural tracking data streams.

The report also summarizes the device selection process implementation elements and evidence gathering activities carried out during pre-FS phase, present the evidence, and an analysis and summary that is intended to inform the upcoming pre-FS device selection decision by the steering committee. The

report closes with remarks regarding FS implementation preparations currently underway and discusses how processes and materials are being adjusted to further support device selection as the project progresses (during the FS and beyond).

2.1 IDEA-FAST Project Background

Fatigue and sleep disturbances are some of the most common issues facing people living with chronic diseases. However current large-scale research in this area rely on self-reported or impractical methods of data collection. Getting better and more reliable data around fatigue and sleep could go a long way in improving people's daily lives.

IDEA-FAST[1] will combine the use of low-cost and accessible technology, such as activity trackers and bed sensors, with more traditional methods of clinical and functional data collection. These digital endpoints can provide a more detailed and reliable picture of the extent of fatigue and sleep disturbances, as well as of the development over time. They will help to reduce patient burden, improve efficiency and enable more rapid development of new treatments.

Figure 2: Participants of an IDEA-FAST workshop discussing technology.

Fatigue and sleep disturbances are common and disabling symptoms that affect patients with NDD and IMID, impacting on daily activities; they are the major predictors of poor quality of life and increased healthcare cost. Current questionnaire-based approaches to measure these symptoms have key limitations preventing them from being used as reliable endpoints in clinical trials to evaluate the effect of therapies.

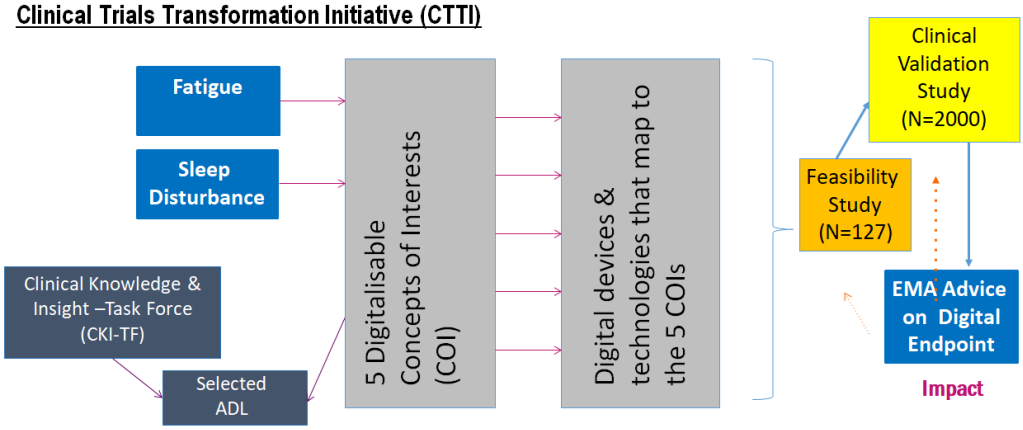

Figure 3: Overview of the relation between device-agnostic digitalisable concepts of interest and the necessity of mapping to selected specific candidate technologies for measurement as a construct for validation through the upcoming feasibility study and following clinical validation study.

Based on the advancement of wearable and portable digital technology, IDEA-FAST aims to address these issues by identifying novel digital endpoints for fatigue, sleep disturbances and disabilities in daily activities. The final ambitious goal is to provide more objective, sensitive, reliable and ecological measures of the severity and impact of these symptoms in real-world settings. Such digital endpoints will eventually improve the efficiency of clinical trials, ultimately reducing the time and cost to bring new therapies to patients.

[1] http://www.ideafast.eu

2.2 Relation of Report and Deliverable to WP3 Organisation and Management

This report and the included deliverable are informed by many activities and groups throughout the project. Most elements, however, are anchored with WP3 "Digital Devices and Technology". The WP is led by Newcastle University (UNEW) as the academic co-lead and Janssen (currently stepping in for Roche as of November 2019) as the EFPIA co-lead[2].

Further contributors are Dreem, Fciências.ID, VTT Technical Research Centre of Finland Ltd, Cambridge Cognition Ltd, Institut Mines- Télécom, McRoberts BV, Takeda Development Centre Europe Ltd, Abbvie Inc., AstraZeneca AB, Eli Lilly and Company Limited, Parkinson's Disease Society of the UK, Pfizer Ltd, SARD / SANOFI (Sanofi Aventis Recherche et Développement), UCB Biopharma SPRL, Orion Corporation and MediBioSense (MBS).

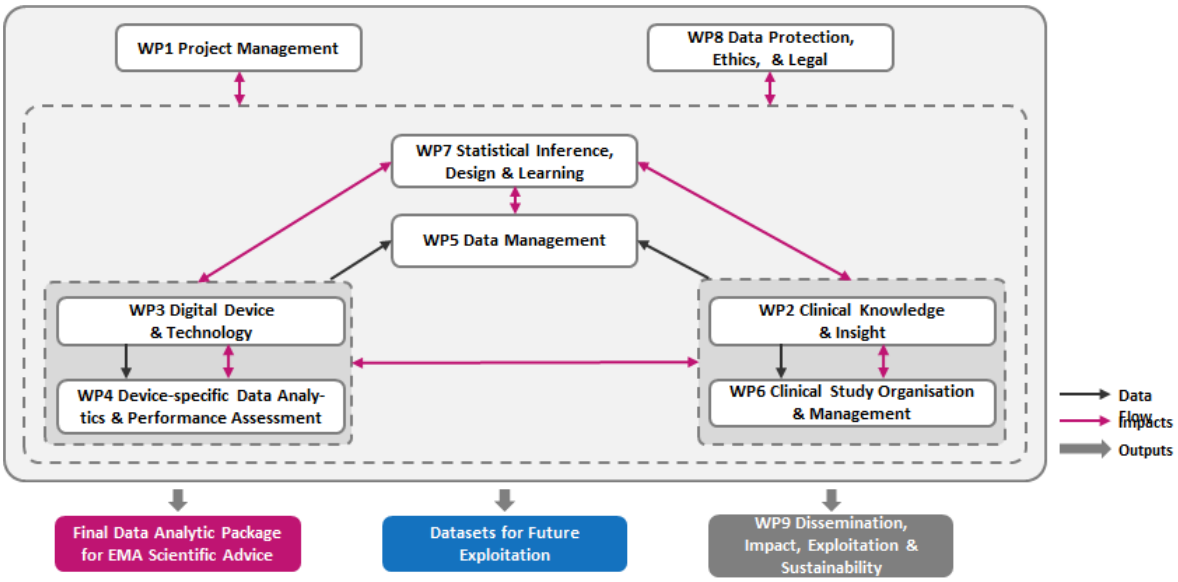

Figure 4: Relation between work packages in the project.

The core purpose of WP3 is defined as facilitating the successful use of digital hardware devices and software applications. This includes coordinating the device selection, according software or application curation and development required to enable successful device use, immediate device data gathering and exchange, providing technical knowledge and support for device or application use, as well as producing design recommendations concerning technology development towards commercialization. This can be paraphrased as "making sure that devices and applications are selected - and their use supported - in such a way that they work for people and for the project".

While the main elements span multiple stages of device selection, as well as application design, development, consolidation, and the implementation of a support and knowledge centre for device and application provisioning and use, this report focuses on the pre-FS phase stage of the device selection element.

This relates primarily to the following two WP objectives:

- O3.1: Provide expert insight/knowledge on digital technology (sensor devices and applications).
- O3.4: Facilitate the selection of the appropriate digital tech. for the feasibility and clinical validation study.

The activities reported on are summarised in Task 3.1 (Facilitate device selection [M1-21]) in the description of the action, which is led by JANSSEN/ROCHE and UNEW, with named additional

[2] Main contacts: Jan Smeddinck at UNEW and Yannis Pandis at JANSSEN.

participants: DREEM, VTT, IMT, McR, FC.ID, SARD. However, major contributions have also been provided by Kiel, GHI, Brescia and other sites.

As outlined in the task description for T3.1, initial testing with devices was performed locally, following protocols described in the following sections and intended to provide information to a device selection for the FS. Early testing was implemented at multiple sites in parallel to cover the considerable range of 9 devices and applications. Procedures were set up to test the specific way devices will be used in the FS. The processes are not intended to form a generic device evaluation or verification (but the project did reach out to device providers to acquire such data, or derived measures, where they exist, to further inform the device selection process). The efforts included device sample procurement and the organization of effort sharing across participating partners with HCI expertise to finalize the feasibility study selection of sensor devices.

The sub-tasks that contained actions that contributed to forming this report are mainly:

- Sub-task 3.1.1 – Gather input on technology selection process and consider device updates
- Sub-task 3.1.2 – Device usability / user-experience pre-testing with experts / convenient subjects

These sub-tasks are hereby being completed. As managed through the task overview tool MS Planner[3] and detailed in the Yearly Action Plan for WP3[4], the main actions carried out that enabled this report can be summarised as:

- A3.1.2a: Procure core devices / applications for testing
- A3.1.2b: Create mapping of device selection criteria to measures and evidence streams
- A3.1.2c: Create materials for gathering evidence on different streams
- A3.1.2d: Set up testing plan including rotation and different sites + timeline
- A3.1.2e: Create materials for gathering evidence on different streams
- A3.1.2f: Complete convenient-subjects evidence collection at all sites
- A3.1.2g: Complete expert assessments (evidence collection) at all sites
- A3.1.2h: Start and maintain device overview (and tech-specs) spreadsheet
- A3.1.2i: Compile pre-FS device selection evidence report for SC

The timelines for the implementation of the pre-FS device selection have been changed relative to the original project proposal and tasks planning due to the accepted project extension request. The request added three months each to the beginning and end of the originally planned project period, effectively extending it from a 60 months duration to a 66 months duration.

The relevant section that concerns actions from WP3 that were designated to begin in the "early-start" period of the initial 3 months (November 2019 – January 2020) reads: "Gather technical details on candidate digital technologies and expert testing of the devices for usability and user-experience for the proposed feasibility study". This effectively moved some actions from the tasks and sub-tasks described above into said period. While the start and end project-months for all other (non-directly affected) tasks and sub-tasks were moved back by three months, the end-date for ST3.1.2 was not adjusted to M8, but remained as M5, leading to an effective delivery date by end of March 2020.

As a notable further consequence, milestone M3.2 had to be split into two parts: M3.2a "Device and application selection", ending at the end of March as well, while M3.2b "Evidence recording procedures and interface for FS" was not pre-dated (as it was not partially fulfilled through pre-dated actions) and therefore remains with a delivery due date of June 30 2020 at the original 5-months offset relative to the original intended start date of February 2020 (now project-month 4 relative to the extended 66 months

[3] The IDEA-FAST MS Planner board

[4] The WP3 Tasks and Actions in Yearly Action Plan

project duration).

The practical management structures that guided the device selection process and materials generation between WP3 and other partners can be summarised as follows:

A Taskforce for Technology Integration (TFTI) was established that bundles the exchange between different technically oriented work-packages, focussing around WP3-5. Through regular TFTI-FSIG meetings, this TFTI also directly interfaces with the Feasibility Study Implementation Group (FSIG) for a coordinated proceeding between clinical and technical aspects of study planning.

For WP3 itself, bi-weekly WP3 Upkeep Meetings were set up for partners who are closely involved. WP3 also offers monthly "WP3 Update Meetings". These TCs are open to all interested parties from the project and are intended as a venue to loosely keep up to date with developments in WP3. Minutes of all meetings are documented in respective folders on a Sharepoint infrastructure that all project members have access to. Additionally, ad-hoc meetings are held as needed (e.g. recently "WP3 Member Roles" meeting). These meetings are documented in the most fitting related running-notes document. Established working file-structures focus around collaborative editing and running meeting notes documents exist for all meetings and key structures and documents. Accordingly, all tasks, sub-tasks, objectives, deliverables, milestones are managed in a shared MS Planner system and have been updated with dates according to the project extension request.

3 Device Selection Criteria, Processes & Documents

The following sections describe working principles for the process for device selection the work on producing the device selection criteria, as well as the related processes and documents / materials that were produced to facilitate the device / application nomination, screening and selection process at the scale of the IDEA-FAST project.

3.1 Working Principles

The working principles for the device selection process were set out in an early meeting in Kiel in November 2019. As much as possible, the intention was to design a process that takes expert assessments and user testing into account to provide a device and application selection that is *data-driven*, informed by requirements that are established and exchanged through the above-mentioned *taskforce interfaces*, and *board-moderated* through providing the best possible evidence to the steering committee so that the device selection can be finalised.

3.2 Device Selection Process Overview

As indicated above, the project includes two main cycles for device and application selection:

1. Pre-FS selection (informed by already available information and pre-testing)
2. Pre-CVS selection (informed by already available information, as well as by insights from the FS and possibly additional parallel studies to focus on additional selection criteria or of promising "late-comers")

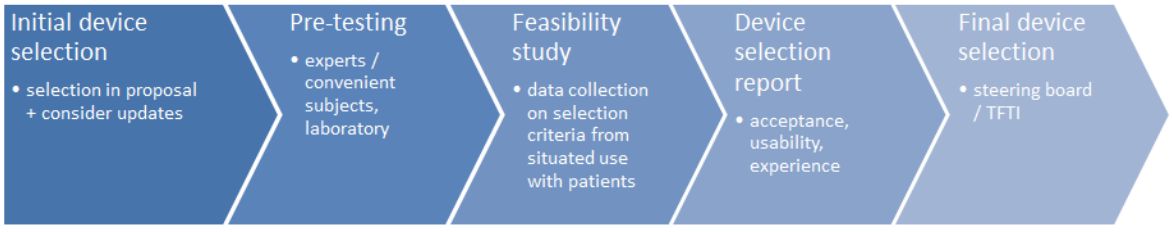

Figure 5: A visualisation of the main device selection process elements over the full project duration.

The figure above separates the coarse two-step process into further elements that need to be carried out over the duration of the entire project, which can help to convey the operationalisation:

- Initial device selection: Which devices to consider for FS?
- Pre-testing: What are candidate device capabilities, how do they perform in early expert and convenient subject testing? Which devices to actually include in the FS?
  -> pre-FS device selection report
- Feasibility study: collect data relative to device selection criteria with different patient groups and more reliably quantifiable scale.
- Device selection report (end of FS): How do devices perform in FS (not only regarding clinical measures but also regarding acceptability, usability, and user experience considering the given use contexts and device / application combinations)?
- Collate all relevant reports and insights + further analysis of data produced by (as opposed to about) devices and applications: Which devices to include in CVS?

In general terms, both processes (pre-FS and pre-CVS selection) have roughly the same structure:

1. Determine devices to consider for selection
2. Shortlisting of devices based on needs considerations and other pre-filtering considerations
3. Determine relevant device selection criteria and weighting
4. Determine evidence types / measures
5. Collect evidence (possibly on multiple evidence streams) for each candidate device / application
6. Analyses based on different evidence streams
7. Collate evidence + generate top-candidates listing
8. Green/red-lighting recommendations

Accordingly, the specific process that was employed during the pre-FS for the IDEA-FAST project comprised of the following key elements:

3.3 Candidate Device Recommendation and Consideration

During a ~ 4-week long device recommendation phase starting in November and ending early December 2019, all project members were invited to recommend the consideration of any additional devices and applications (cf. ST3.1.1 and A3.1.1a). This effectively resulted in a snowball-sampling approach of candidate technologies, as early investigations into a more exhaustive global market scan had proven impractical based on the large number of potential candidate technologies across all wearable and stationary sensor devices and applications.

During and following the initial device recommendation phase (during project planning + dedicated ~4-week phase in the beginning of the project), candidate technologies were collected in a devices overview[5] (see Attachment 01). For all suggested technologies, teams at different sites collected detailed publicly available information that falls broadly into the following categories:

- General Device Information
- Health Measures
- Technical and Other Features
- Additional Considerations

This information was based on online documentation, CE-marking documents, instruction materials and other publicly available sources. The information was then considered at face-value to inform a decision about whether to consider the candidate technology for closer investigation. Closer investigation meaning aiming to acquire a (small) sample of the technology (hardware device(s) or software licence(s))

[5] Direct online file link: IDEA-FASTDevicesOverviewTemplate

for hands-on testing with experts, convenient subjects and patient specialists.

Due to facing large number of candidate devices, the reasoning for tabling technologies for closer investigation was based around the following possibly applicable rationales / pragmatic arguments:

a. The technology was included as a clinically informed candidate technology at project proposal stage / the technology provider is a project member.
b. The technology represents an updated version or closely related improved development to a technology already included.
c. The technology provides a measure that has reasonable potential to map to a relevant project concept of interest and that is not yet accessible through another candidate technology.
d. The technology would fit a location (either on the body or in a relevant location of daily living) that is not yet occupied by another candidate technology.
e. The technology represents a technology-generational advancement over a comparable already considered candidate.

Figure 6: A workshop participant trying an "earable" as an example of a technology that was not included in the original proposal, but more closely investigated following the device recommendation stage due to occupying a novel body location.

Technology Selection Criteria, Weighting and Mapping to Evidence Streams

Through a committee-based process that included multiple refinements (cf. A3.1.1b: Invite comment on device selection criteria) seeking feedback on fit and importance of criteria from project partners, including EFPIA partners, a list of device selection criteria that the consortium deems relevant was established. The selection criteria were subsequently categorised and cover the following key areas of concern (listed with number of principal criteria per category and mean importance as rated across all criteria per category for the pre-FS selection phase):

a. Data Quality, Reliability & Analytics *(10 principal criteria; mean importance: 1.9)*
b. Data Access, Transparency & Handling *(7 principal criteria; mean importance: 3)*
c. Accessibility, Usability & User Experience *(21 principal criteria; mean importance: 3.1)*
d. Regulatory Concerns *(7 principal criteria; mean importance: 2.9)*
e. Scalability *(10 principal criteria; mean importance: 2.4)*
f. Track Record & Data Availability *(5 principal criteria; mean importance: 1.8)*

The collection, commentary and refinement process resulted in a list of 50 principal criteria, where some criteria (such as mapping of sensor output to concepts of interest) contain assessments against multiple sub-criteria.
In order to inform efforts for evidence generation and the later pre-FS technology selection process, the relevance of each criterion was rated on a scale from 1 (min ≈ can ignore) to 5 (max ≈ crucial) to assess

its importance for the pre-FS selection process from the perspective of WP3. A basic consideration was also added, whether evidence to inform the criterion can most reasonably be produced through input from work with users, experts, or both. The resulting device selection criteria list[6] is available as Attachment 02.
Informed by this need to produce user / convenient subject based and expert based evidence streams, experience diaries, experience questionnaires and expert evaluations / assessments were selected as fitting methods that are detailed in the following sections.
These evidence streams can be collated with the existing publicly available / manufacturer provided information, as well as with information from an early literature review carried out by other project partners (led by WP4). In a further device selection criteria table[7] that is available as Attachment 03, the device selection criteria were then mapped against these evidence streams, taking note of the plausibility of mapping meaningful input. This was necessary to reduce the workload of generating input for every cell, as well as to inform the actual elements of the experience diaries, questionnaires and expert evaluation in the design phase of these tools, as they were purpose-built to map to the device selection criteria they were meant to inform.

3.4 Public Information Gathering

As outlined above, public information was included as much as possible to inform an early impression on candidate devices selected for consideration. While manufacturer-provided publicly available information from websites, product fact sheets, manuals, reports and reviews, CE-marking documentation, etc. was collated as far as possible for each suggested candidate device (a large two-digit count), an early literature review led by WP4 considered only candidate devices selected for closer investigation (a small two-digit count).

3.5 Experience Diaries

To allow for capturing complex and possibly unexpected feedback from testers who engaged in prolonged periods of technology use for testing (from one day to multiple weeks), an experience diary was created. The IDEA-FAST Device and Application Experience Diary[8] is available as Attachment 04 and also as part of the long-form questionnaire described below. The diaries were intended primarily for use with convenient subjects who are not members of one of the designated affliction groups that the project focuses on. The meta-data section was designed to allow for reporting during use, immediately after use, or back-dating to an episode of prior use. Following a semi-structured paradigm and intending to inform overarching key considerations that each cover multiple device selection criteria (cf. Evidence Gathering and Assessment Strategy), the diary form invites commentary on the following elements:

- General experience (of technology use)
- Technical issues ...
- Time and effort required ...
- Acceptability (/ fit for use in everyday live) ...
- (Any further comments)

3.6 Experience Questionnaires

As an essential tool for collecting evidence on device selection criteria that technology test users can conveniently speak to (i.e. especially around *Accessibility, Usability & User Experience*, which was also the category of device selection criteria judged to be most relevant overall in the pre-FS selection phase), a

[6] Online version: IDEA-FASTDeviceSelectionCriteriaDescriptions

[7] Online version: IDEA-FASTDeviceSelectionCriteriaMapping

[8] Online version: IDEA-FASTExperienceDiaryTemplate

device experience questionnaire was designed. Next to basic demographic information and input fields to describe the device / application used, as well as the usage context, the questionnaire mainly contains a battery of questions that was specifically designed to map to those device selection criteria that users can express a meaningful opinion / position about. In order to avoid overburdening respondents, the questionnaire typically contains one question item that directly maps to a related selection criterion. In order to improve reliability in the absence of cross-validation and negated items, all questions are posed as Likert-scale agreement items with the same edge values for consistency and to allow for parametric statistical analysis, although non-parametric statistics might be preferable as a more conservative precaution.

A long-form[9] and short-form[10] version of the questionnaire have been designed to fit different application scenarios. Both are available as Attachment 05.

While the short-form version is intended mainly for use in workshop settings, or with testers who have limited availability or capacity to spend considerable effort completing a questionnaire and will typically require 3 – 8 minutes to complete, the long-form version – which can take between 5 and 25 minutes to complete based on highly dynamic usage options – was intended for use with project internal convenient subjects, or participants of prolonged testing periods. In addition to the elements described above, the long-form questionnaire also contains validated scales for usability (i.e. the System Usability Scale[11]), frustration (as a subscale of the NASA Task Load Index[12]), as well as the possibility to also report on the experience with an application that was used in conjunction with – or independently of – a given sensor device and finally the option to also complete an included version of the experience diary, which covers the semi-structured free response fields described in the section above.

Figure 7: Participants of one of the hands-on workshops carried out as part of the IDEA-FAST project exploring, testing and discussing different wearable sensor devices. The setting provides an example of a use case for the short version of the experience questionnaire described above.

3.7 Expert Evaluations

Since the user-testing could only inform a sub-set of the device selection criteria that are mostly from the same category and since the publicly available information on the technologies is not always reliable, expert evaluations were set up to facilitate an additional stream of evidence. The focus in the device selection criteria that are highlighted in the expert evaluation is on those categories and criteria that

[9] Online version of questionnaire IDEA-FASTLongExperienceQuestionnaire and questionnaire templateIDEA-FASTLongExperienceQuestionnaireTemplate.

[10] Online version of questionnaire: IDEA-FASTShortExperienceQuestionnaireand questionnaire template: IDEA-FASTShortExperienceQuestionnaireTemplate.

[11] Brooke J. "SUS-A quick and dirty usability scale." Usability evaluation in industry [Internet]. CRC Press; 1996. Available from: https://www.crcpress.com/product/isbn/9780748404605

[12] Hart, S. G., & Staveland, L. E. (1988). Development of NASA-TLX (Task Load Index): Results of empirical and theoretical research. *Human Mental Workload*, *1*(3), 139–183.

would not otherwise be covered by user-based or independently verified publicly available information (namely *Data Quality, Reliability & Analytics*, *Data Access, Transparency, and Handling*, as well as *Scalability*) and that experts are in a good position to judge based on having worked closely with the technologies during a 4 – 8 weeks testing period. The expert evaluation form[13] is available as Attachment 06.

In order to allow for a more balanced impression, the expert evaluation was set up with the intention that multiple experts at multiple – largely independent – sites employ the template to assess the same range of technologies under close consideration. A collated examination can then further inform the technology selection process.

3.8 Evidence Gathering and Assessment Strategy

In the case of IDEA-FAST, a device and application testing and assessment rota was set up that spanned multiple primary and secondary sites. While primary sites aimed for testing – as far as possible – the full set of technologies designated for closer consideration, the secondary sites served to facilitate spotlight evaluations of technologies that require special technical capabilities or access to specific user groups (e.g. the different disease affliction groups).

For practical purposes a round robin rota was established with a fixed order including all project member sites involved in testing. Upon completion of assessment of any given technology at one site it was then passed down the line to the next site as soon as possible. Towards the end of the testing period this allowed for streams of evidence from multiple sites to be gathered through each method / type of evidence stream, which was deemed important given the nature of the project, where some project partners are also technology providers.

Where possible, outcome data were subjected to intermediary analysis. For the publicly available information this meant a structured mapping against device assessment criteria. The experience diaries were subjected to outcome-oriented / deductive coding to map experience statements against the device selection criteria. This can be achieved by working with qualitative evaluation technologies, such as NVIVO and reliability can be improved through cross-checking by multiple researchers. Where possible – i.e. given a sufficient number of responses - the experience questionnaire outcomes were analysed using quantitative (due to working with very different technologies largely descriptive) statistics. The expert evaluations were collated to allow for combined consideration.

Since the pre-FS evidence collection phase produced multiple concurrent and difficult to collate streams of evidence, a green/amber/red-lighting system was set up to abstract a practically applicable interpretation. Based on a sighting of outcomes and intermediary analyses, a summary score was provided for each evidence stream by technology experts. The template document for this collation of evidence is available as the worksheet titled *Criteria Mapped to Devices*[14] in Attachment 03.
A For a better overview and to enable coarse summaries, means of all scores provided for each category were also calculated in order to produce a per-device overview based on the device selection criteria categories that allows for a focused highlighting of strengths and weaknesses, together with core considerations that came to light during the testing and evaluation period. The structure for such a per-device report item is highlighted in an exemplary fashion below:

3.8.1 Device A (Core / Additional)

Device description based on publicly available information. Lorem ipsum dolor sit amet, consectetur adipiscing elit. Sed sollicitudin molestie nisi, ut euismod ante blandit ut. Phasellus interdum quam at lacus suscipit, in eleifend felis dapibus. Nam orci lacus, laoreet accumsan condimentum ac, pharetra sit amet nisl. Phasellus ac dignissim neque. Maecenas aliquam metus nec felis molestie, eget pretium urna suscipit.

[13] Online version: IDEA-FASTExpertEvaluationTemplate

[14] Online version: IDEA-FASTDeviceSelectionCriteriaMapping

Morbi dui augue, rutrum at dui ut, suscipit dignissim felis. Nam quis cursus lacus. Nunc id magna rhoncus, dictum leo elementum, pretium odio. In vehicula risus est, nec faucibus diam maximus nec. Sed auctor in neque non tincidunt. Nulla facilisi.

Selection Criteria Category	Score	Comments
Data Quality, Reliability & Analytics	X.Y	*Elements of rationale for score...*
Data Access, Transparency & Handling	X.Y	*Elements of rationale for score...*
Accessibility, Usability & User Exp.	X.Y	*Elements of rationale for score...*
Regulatory Concerns	X.Y	*Elements of rationale for score...*
Scalability	X.Y	*Elements of rationale for score...*
Track Record and Data Availability	X.Y	*Elements of rationale for score...*

Excerpts from experience reports:

- *"Negative sentiment statement A."* [device selection criterion]
- *"Negative sentiment statement B."* [device selection criterion]
- *"Positive sentiment statement A."* [device selection criterion]
- *"Positive sentiment statement C."* [device selection criterion]

Recommendation: Include/Exclude

Comments: *Any further comments, especially regarding further operationalisation of the technology.*

For finalising the recommendation, with any device that had been included in the project plan from the start based on clinical consideration, the evidence was interpreted seeking tangible reasons for ***exclusion***, while for any additional technologies, the evidence was interpreted seeking tangible reasons for ***inclusion***.

3.9 Process Outlook

In current developments the process and materials as described above are being adjusted for use during the feasibility study phase with two main aims: 1) Adjust evidence gathering tools to support to specific setting of the feasibility study, focusing on capturing patient perspectives. 2) Adjust and streamline the processes to allow for any potentially required consideration of additional technologies in parallel to the feasibility study in order to allow the project to remain open should unusually promising additional technologies, or updated versions of technologies already included become available during the feasibility study and analysis phase (~ 1 year) given the fast-moving market and technology development.

4 Ongoing and Future Work

Moving from the pre-FS device selection towards immediate FS preparations and the evidence gathering phase that is the feasibility study itself, the range and weighting of selection criteria, as well as the according processes for gathering evidence are being adjusted for facilitate both application in the feasibility study, as well as in possible smaller-scale parallel investigations, as described above.

Slight adjustments have also been made as additional precautions in the light of the current coronavirus / Covid-19 situation. An according element has been added to the risk assessment in the Yearly Action Plan for WP3 and is being updated on a regular basis. While the general proceedings of WP3 are currently not majorly affected, a number of contingency-planning efforts have been triggered. This includes scouting options for off-site storage of devices and tighter cleaning protocols before recycling devices. Requests for updates on expected device delivery timelines have been sent to all device providers of current candidate devices for inclusion in the FS. At this point there have been no responses that indicate

difficulties in supplying the number of devices required.

4.1 Process and Methods for the Feasibility Study

According with clinical requirements and strategy, the FS will include a wide array of self-reported fatigue and sleep assessments, Assessment of HR-QoL and potential confounders, etc. A number of tools are included specifically for measuring the acceptability, usability and user experience of the included technologies.

Validated measures included at the end of each of the recurring ~ 2 week periods of use of different devices are the *Comfort Rating Scale*[15], a 6-item (approx. 2 min) measure investigating the comfort of a wearable device on a 21-point ordinal scale from '0 – low agreement' to '20 – high agreement', as well as the *System Usability Scale*[16], as a commonly used, validated 10-item (approx. 3 min) questionnaire that asks users to rate a device on a 5-point Likert scale from '1 strongly disagree' to '5 – strongly agree'. Questions focus on the ease of use of the technology, and the integration of various functions within it. In addition, a short 16-item adjusted version of the short experience questionnaire described above (approx. 7 min) is included that was used and tested with more than 200 subjects and improved during the pre-feasibility-study device selection process. It maps explicitly to the device selection criteria which are very relevant to inform the project in its progression towards the CVS and captures many dimensions that are not possible to capture as such through existing validated questionnaires. Lastly, an adjusted version of the five-item experience diary will also be collected (approx. 2 min per technology, if the option for audio-recording is employed). These items have been used, tested and improved in the pre-feasibility-study period as described above and allow patients to raise issues that may not have been considered by the study design and are therefore not explicitly captured by the remaining study tools. Clear guidance will be provided to assure that brief responses are submitted, as to reduce the burden of reporting.

4.2 Device and Application Data Pathways for the Feasibility Study

The pre-FS phase focussed on assessments around acceptability, usability and user experience through work with experts and users. Exemplary data sets were also collected to assess data processing and quality from an expert perspective (in collaboration with WP4).

However, during the FS, a systematic data collection with participants from all affliction groups over multiple weeks will form a central additional element of evidence gathering (cf. ST3.2.2 and 3.3.1). Collecting the data is central to the core aims of the project, in order to allow for the cross-validation of the different measures, as well as for further analysis regarding reliability and crucially exploring mappings to the concepts of interest. The general data collection and processing pipeline for IDEA-FAST is outlined in Figure 8.

[15] Knight JF, Baber C, Schwirtz A, Bristow HW. The comfort assessment of wearable computers. In: Proceedings Sixth International Symposium on Wearable Computers. 2002. p. 65–72.

[16] Brooke J. "SUS-A quick and dirty usability scale." Usability evaluation in industry [Internet]. CRC Press; 1996.

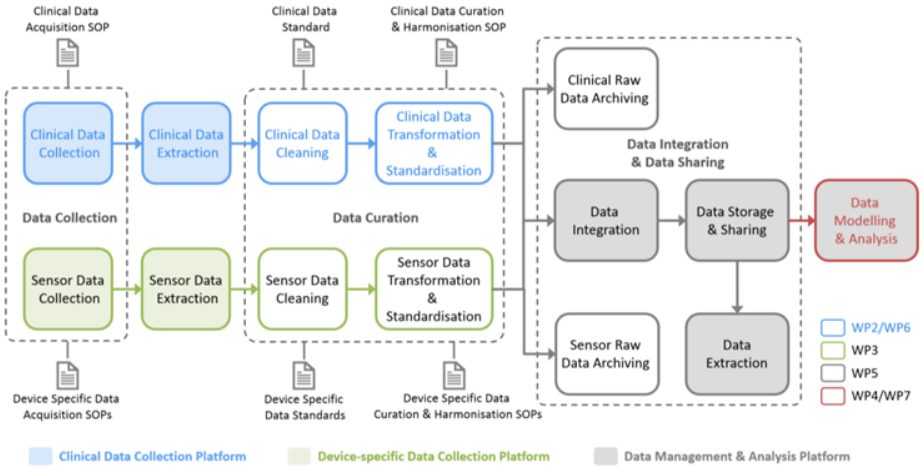

Figure 8: The general data collection and processing pipeline for IDEA-FAST, showing separate collection of clinical and sensor / application data. This advanced version shows the concept to be realised during / after the FS and for the CVS.

In order to support initial execution of the FS, the solid green elements need to be guaranteed through technological provisioning facilitated by WP3 and in close collaboration with WP5 (mainly through the TFTI).

Hence, in a simplified view, as illustrated in Figure 9, for each type of device data in the FS, we are implementing a standardised and secure data transfer pipeline, to ensure that all data can be integrated on the IDEA-FAST data management platform.

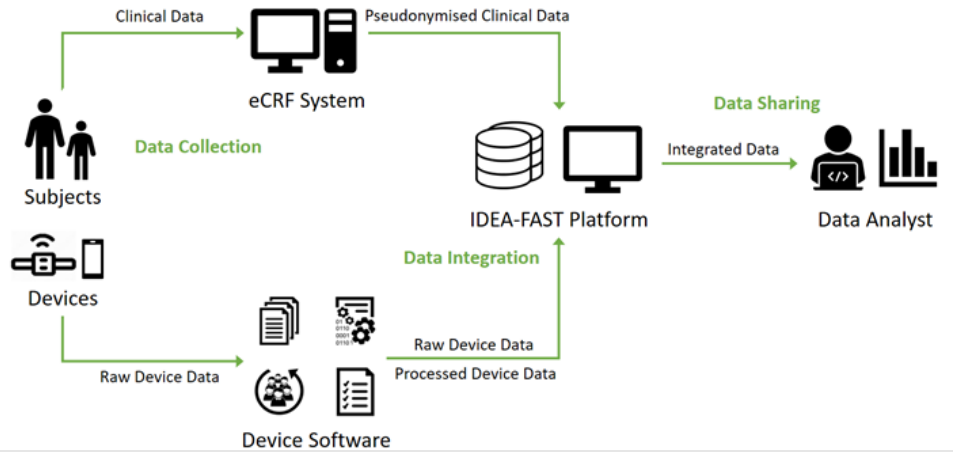

Figure 9: Schematic overview of the data collection for the feasibility study in IDEA-FAST.

While a specific secure and robust process will be documented for each data-producing device and application, there are four general categories of data transfer pipelines that cover all possible scenarios:

a. Data is sent directly from the device to a device provider's servers using secure file transfer. Data will then be sent in encrypted packages to the IDEA-FAST platform.
b. Data captured by an app on the provided study smartphone. It then follows the process described in a).
c. Data is captured by an app on the provided study smartphone. Data will then be sent to the IDEA-FAST platform directly in encrypted packages.
d. Data is captured manually by local wired or wireless read-out by study support staff, either in-place at the participants' home, or after a device has been returned to the study centre. Data will then be sent in encrypted packages to the IDEA-FAST platform.

The meta-data for any device or application data captured during the study will not contain patient names or any other direct personal identifiers. The data management platform will be hosted in secure servers provided by Imperial College London (ICL), the consortium partner responsible for the overall data management of the IDEA-FAST project. At the point of transfer to the data management platform, each file will be labelled in a standardised format, including information on: Study centre, participant unique ID, device ID, data source/ modality, device or application ID, and time point (YYYY_MM_DD). For example: "centre 01, participant 001, device_5425_0234, XYZ_Sensor_Data, IDF_dev_mcr_0001, 30 August 2020" will be listed as "01_001_ XYZ_Sensor_2020_08_30". To avoid mistakes when copying the device ID, a system that automatically checks if the number provided is a valid device number (akin to credit card numbers that can be checked if they exist) will be employed. The metadata of each device data type will also be provided along with the processed data. This information will be stored in the encrypted package together with the device data and is not readable to third-parties during transfer. After each device use period and data storage, the device will be reset (and thoroughly cleaned) and all local data erased before the device is redistributed.

5 Conclusions

This report presented the device selection process and materials for the IDEA-FAST project, focussing on pre-feasibility study phase and summarising adjustments towards the feasibility study phase. The upcoming feasibility study assess in how far the data produced by the included technologies can support measures that map to five digitalisable concepts of interest and it will also collect data on the acceptability of the devices in order to inform a further selection of devices towards a large-scale clinical validation study.

This report provides information on the device selection criteria, processes and documents produced in the pre-FS phase of the project, forming the first deliverable that is part of work-package (WP) 3 "Devices and Technology" (deliverable D3.1 [project internal numbering] or 8 [in the project officer count]: Device selection criteria and documents / processes for gathering evidence). This includes the rationale and development report for device selection criteria as well as evidence collection processes and materials (as designed for and employed in pre-FS phase, together with - where applicable - adjustments in preparation for the FS).

While the information gathering and technological, as well as procedural provisioning was implemented in WP3, the final decisions on device and application selection will be made by the Steering Committee, which is representative of the multi-faceted project member interests. This final selection step also offers a further opportunity to reflect on the device selection criteria and to adjust them as needed.

The processes documented in this report and the template materials created are made available as a public contribution by the project, as they may be informing or be employed as is – or in adjusted form – in a growing number of like-minded projects that face the challenge for selecting the most reasonably promising candidate technologies from a global market that provides hundreds of candidates.

6 Acknowledgments

This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 853981. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation program and EFPIA.

The WP3 co-leads would like to thank all project members who supported the production of this report and all materials contained or referenced in it. This includes the Device Testing Group at Newcastle University, as well as all pre-study and workshop participants at Open Lab, Dance City and during the project kick-off week.

7 Disclaimer

This communication reflects the view of the IDEA-FAST consortium and neither IMI nor the European Union and EFPIA are liable for any use that may be made of the information contained herein.

8 Appendices

The appendices / attachments are listed in order here, together with links to online versions of the documents. Where applicable, printed documents then follow in order.

8.1 Attachment 01 – Device Overview

IDEA-FASTDevicesOverviewTemplate

8.2 Attachment 02 – Device Selection Criteria Description

IDEA-FASTDeviceSelectionCriteriaDescriptions

8.3 Attachment 03 – Device Selection Criteria Mapping

IDEA-FASTDeviceSelectionCriteriaMappingTemplate

8.4 Attachment 04 – Experience Diary

IDEA-FASTExperienceDiaryTemplate

8.5 Attachment 05 – Experience Questionnaires

IDEA-FASTShortExperienceQuestionnaire

IDEA-FASTShortExperienceQuestionnaireTemplate

IDEA-FASTLongExperienceQuestionnaire

IDEA-FASTLongExperienceQuestionnaireTemplate

8.6 Attachment 06 – Expert Evaluations

IDEA-FASTExpertEvaluationTemplate

IDEA FAST

1. Which devices to consider for FS?
2. What are candidate device capabilities (as indicated in specs / documentation)?

*** Device selection criteria / testing results will be in separate structure!**

Usage notes:

leave fields empty if we d

Assessor Name(s)

General Device Information

Device Reference	Device Name	Device Set [original core, updated core, additional]	Provider	Website	Our Contact	Description	Platfom/Software type	main material (skin contact)	Location

lon't know (yet), put "n" or "no" or "false" if verified that way, put "y" or "yes" or "true" if verified that way (can append further comments), put N/A if category does

			Health Measures (From Information Material Only - Not Testing!)									
Type	CE-Mark General/Medical/Else	CE Marked as Medical Device?	CE-Mark Intended Use	Safety Class	electrocardiogram (ECG)	photoplethysmogram (PPG)	photoplethysmogram (PPG)2	Blood volume changes/Blood Pulse	electrodermal activity (EDA)	electroencephalogram (EEG)	Electromyography (EMG)	Energy expenditure (EE)

not apply (e.g. due to device type, such as no material with skin contact in bed sensor)

diet induced thermo genesis (DIT)	Body (Skin) Temperature (thermistors)	Body Posture	Heart Rate (HR)	respiratory rate (RR)	basal metabolic rate (BMR)	Oxygen Saturation (OS)	Metabolic Equivalent of Task (METS)	Sweat	Steps	sleep	Stress Indicaton	wear time validation (WTV)

Technical and Other Features (From Information Material Only - Not Testing!)

Battery life [hrs]	Sensor Summary	logging frequency	Output Data Aggregation	Data Interface,version	accelerometer	gyroscope	thermometer	light sensor	Different measurement mode	Total charging time	storage capacity	connectivity

				Additional Considerations								
weight	dimensions	Band size (Measured in Bent arm circumfence /	operating temperature	dust tight	Electral Power Supply	water resistant	Cost Any	Exchange	Consider for testing (Y/N)	Rationale	Order Count	Unit Cost (spent) [GBP]

Date Ordered	Date Received	Capacity to deliver devices by June (April	Capacity to deliver 50 devices by July (April

Device Selection Advice from External Experts

External experts have tested numerous devices with patients. Manufacturers tend to send group of devices to test. These devices include some of those IDEA FAST is considering. Advice below, stems from multiple evaluations (see also https://www.nature.com/articles/s41746-019-0082-4):

Our criteria (see below), and the mixed methods approach appear appropriate. Following considerations can inform meta-analysis, rather than specific evidence collection methods.

Main Selection Factors

There are three main factors that determine whether a device will be used/useful - their weighting will depend on our research aims/questions. Technical (including data criteria, regulatory concerns) and two usability / user experience factors: user burden and user acceptance. Our criteria can map to these factors. User acceptability also covers concerns from other stakeholders, such as partners and carers.

Criteria

Prioritising device selection criteria for pre-feasibility study:
[importance in pre-FS stage: 1-5; evidence can be collected from: experts/users]
1: might get ignored
2: somewhat important (but secondary)
3: important
4: very important
5: deal-breaker

Data Quality, Reliability & Analytics

- data accuracy (low variance) [2;e]
- data consistency (few data gaps) [2;e]
- duration of "daily wearing" required to capture telling data [2;e]
- data reliability (consider artificial re-test reliability) [1;e]
- predictive power of outcome data for known gold standard outcome measure (for the 5 concepts in IDEA-FAST) [1;e]
- low/no calibration (or only seldom and low effort to do so) [3;e]
- what validated digital outputs available? How can these digital outputs be mapped to the 5 concepts of interests of IDEA-FAST (e.g., physical activity, biophysiology, neuropsychological performance, EEG and social parameters)? [1;e]
- what "exploratory" (i.e., potential available but not yet validated by the manufacturer) digital outputs are available – e.g., stress-levels, sleep quality indices, "readiness index", ECG, respiratory rate etc? How can these digital outputs be mapped to the 5 concepts of interest of IDEA-FAST. [1;e]

Data Access, Transparency, and Handling

- good interoperability (Score API for ease-of-developer-use, consistency and stress test) (for algorithm developers) [3;e]

    - how the data from the device are extracted or transferred to the IDEA-FAST data management platform? E.g., will the data be stored on the device until the device returned to the researchers? Will the data be uploaded via internet to the SME data platform?
    - adherence to standards for output/interfacing (Common data format, such as csv, HDF5, HL7, etc.) [3;e]
- documented algorithms/data-processing pipeline (no black box) [1;e]
- connectivity (modern standard, high reliability and adequate throughput) (for operators) [3;e]
- requirements for platform (e.g., does it only run on iphones, or android or some other OS) [4;e]
- full raw data access (mandatory binary check) [4;e]
- documented algorithms/data-processing pipeline (no black box)

Accessibility, Usability and User Experience

- device comfort (using validated ergonomics) (for end users) [4;ue]
- no high temperature development (when in use) [2;ue]
- convenience of required wearing duration [3;u]
- usability (e.g., SUS; also consider included software interfaces if applicable) (for operators, e.g., clinicians) [4;u]
    - Device frustration [4;ue]
    - Application frustration [3;ue]
- user experience [4;ue]
    - Perceived usefulness [2;u]
    - Perceived representativeness/trustworthiness of data [2;u]
- ruggedness [2;ue]
- connectivity (most likely with phone) [3;u]
- hygiene (e.g. how easy to clean … does it dirty easily) [4;ue]
- device visual acceptability [4;u]
- application visual acceptability [3;u]
- can technology be combined with potential other required devices? [3;e]
- device unobtrusiveness (does it get out of the way as much as possible) [3;ue]
- application unobtrusiveness (does it get out of the way as much as possible) [2;ue]
- setup to use time for professionals [3;e]
- onboarding / setup to use experience for users [3;u]
- is the device designed for use 24/7 or only for specific activities (e.g., sleep)? Or have to be removed for certain activities (e.g., shower/swim etc.) [4;e]
- location [4;e]

Regulatory Concerns

- CE marked [5;e]
- CE mark intended use conformity [4;e]
- safety of device use [4;e]
- FDA/FCC approval [1;e]
- GDPR conformity (of potential companion app) [4;e]
- HIPAA conformity (of potential companion app) [1;e]
- instruction manual available in all languages of the 11 countries of IDEA-FAST? [1;e]

Scalability

- device battery runtime (if applicable) and possibility to charge easily/quickly [4;eu]
- application impact on smartphone battery [2;e]
- cost per unit [4;e]
- cost for support (also consider cost per user-month or similar to better compare across systems with disposable and noon-disposable elements) [1;e]
- quality of support and information materials [1;u]
- cost for consumables during use? (e.g., do sensors need to be replaced?) [3;e]
- reusability [4;e]
- cost for reuse [2;e]
- ease of reuse [2;e]
- estimated app-adjustment +/ data integration cost [1;e]

Track Record and Data Availability

- peer-reviewed publications of studies in which the technology has been validated with performance assessment [3;e] (meta-analysis)
- other publications/material/study data convincingly demonstrating performance in different settings [3;e] (meta-analysis)
- has the device been validated with healthy volunteers? [1;e]
- has the device been validated with the disease populations relevant to IDEA-FAST? [1;e]
- has the device been tested in other disease populations (and data available)? [1;e]

Numbers in (brackets) refer to previously listed criteria. Criteria grouped below for simplicity.	User Review	Expert Review	WP3 Importance (1-	Captured by WP3 Methods - Yes, Maybe (No = empty)					
				Literature Review	Manufacturer-provided Information	Experience Diaries	Experience Questionnaire - internal,	Experience Questionnaire - external,	Expert Review Spreadsheet
Data Quality, Reliability & Analytics									
data accuracy (low variance) [2;e]		Y	2						Maybe
data consistency (few data gaps) [2;e]		Y	2						Yes
Duration of "daily wearing" required to capture telling		Y	2						Yes
data reliability (consider artificial re-test reliability) [1;e]		Y	1						
predictive power of outcome data for known gold standard outcome measure (for the 5 concepts in IDEA-		Y	1						
low/no calibration (or only seldom, if required only rarely		Y	3						Yes
what validated digital outputs available – e.g., ECG,									Yes
concepts of interests of IDEA-FAST (e.g., physical activity, biophysiology, neuropsychological performance, EEG and		Y	1						Yes
what "exploratory" (i.e., potential available but not yet validated by the manufacturer) digital outputs are available – e.g., stress-levels, sleep quality indices,									Yes
How well do these expoloratory digital outputs map to the 5 concepts of interest of IDEA-FAST. [1;e]		Y	1						Yes
Data Access, Transparency, and Handling									
good interoperability (Score API for ease-of-developer-use, consistency and stress test) (for algorithm		Y	3						Yes
how the data from the device are extracted or transferred to the IDEA-FAST data management platform? E.g., will the data be stored on the device until the device returned									
adherence to standards for output/interfacing (Common data format, such as csv, HDF5, HL7, etc.) [3;e]		Y	3						Yes
documented algorithms/data-processing pipeline (no		Y	1						Yes

connectivity (modern standard, high reliability and		Y	3						Yes
requirements for platform (e.g., does it only run on		Y	4						Yes
full raw data access (mandatory binary check) [4;e]		Y	4						Yes
Accessibility, Usability and User Experience									
Device comfort (using validated ergonomics) (for end	Y	Y	4			Maybe	Yes (direct)	Yes (direct)	Yes
Device does not get hot during (typical) use	Y	Y	2			Maybe	Maybe	Maybe	Yes
Convenience of wearing device for (typically) required	Y		3			Maybe	Yes	Yes	
Usability (with two further sub-criteria)			4			Maybe	Yes	Yes	
- Device frustration	Y	Y	4			Maybe	Yes	Yes	Yes
- Application frustration	Y	Y	3			Maybe	Yes	Yes	Yes
User experience (with two further sub-criteria)	Y	Y	2			Yes	Yes	Yes	Yes
- Perceived usefulness of the device/application	Y		2			Maybe	Maybe	Maybe	
- Perceived representativeness/trustworthiness of data	Y		2			Maybe	Maybe	Maybe	
Ruggedness/robustness of device	Y	Y	2			Maybe	Maybe	Maybe	Maybe
Connectivity from device to (most likely) phone	Y		3			Maybe	Yes	Yes	
Hygiene (e.g. how easy is the device to clean? Does it get	Y	Y	4			Maybe	Yes	Yes	Yes
Device visual acceptability (e.g. is the device visually	Y		4			Maybe	Yes	Yes	
Application visual acceptability	Y		3			Maybe	Yes	Yes	
Can device be combined with potential other required		Y	3						Yes
Device unobtrusiveness	Y	Y	3			Maybe	Yes	Yes	
Application unobtrusiveness	Y	Y	2			Maybe	Maybe	Maybe	
Time required to setup, for health professionals		Y	3						Yes
User experience of onboarding/setup device ready for use	Y		3			Maybe	Yes	Yes	
Device for continual use (24/7) or only for specific activities (e.g., sleep)? Does device have to be removed for		Y	4						Yes
Location(s) [on the body or in the room]:		Y	4				Yes	Yes	Yes
Regulatory Concerns									
CE marked [5;e]		Y	5		Yes				
CE mark intended use conformity [4;e]		Y	4		Yes				Yes
Safety of device use [4;e]		Y	4						Yes
FDA/FCC approval [1;e]		Y	1		Yes				

GDPR conformity (of potential companion app) [4;e]		Y	4		Yes				Yes
HIPAA conformity (of potential companion app) [1;e]		Y	1						
instruction manual available in all language of the 11 countries of IDEA-FAST? [1;e] (meta-analysis, not testing … we will need to prepare FAQ sheets + support videos for		Y	1		Yes				
Scalability									
device battery runtime (if applicable), plus possibility to	Y	Y	4		Yes		Yes		Yes
Application impact on smartphone battery [2;e]		Y	2						Maybe
cost per unit [4;e]		Y	4		Yes				
Cost for support (also consider cost per user-month or similar to better compare across systems with		Y	1						Maybe
Quality of support and information materials [1;u]	Y		1						
cost for consumables during use? (e.g., do sensors need to		Y	3		Maybe				Yes
reusability [4;e]		Y	4		Maybe				Yes
Cost for reuse [2;e]		Y	2						Maybe
ease of reuse [2;e]		Y	2						Maybe
estimated app-adjustment +/ data integration cost [1;e]		Y	1						Maybe
Track Record and Data Availability (Mark Van Gills and									
peer-reviewed publications of studies in which the technology has been validated with performance		Y	3	Yes					
other publications/material/study data convincingly demonstrating performance in different settings [3;e]		Y	3	Yes					
has the device been validated with healthy volunteers?		Y	1						
has the device been validated with the disease		Y	1						
has the device been tested in other disease populations? If		Y	1						

Rank device/criteria as green (3)/ amber (2) / red (1), where possible. Begin with higher priority criteria. XD = experience diary ranking, XQ = experience questionnaire ranking, EE = expert evaluation ranking

	User Review	Expert Review	pre-FS Importance (1-5)	Device A			Device B			Device C		
				XD	XQ	EE	XD	XQ	EE	XD	XQ	EE
Data Quality, Reliability & Analytics												
data accuracy (low variance) [2;e]		Y	2		N/A	3		2	3		3	2
data consistency (few data gaps) [2;e]		Y	2		N/A	3		2	3		3	3
Duration of "daily wearing" required to capture telling data [2;e]		Y	2		2	2		2	3		3	3
data reliability (consider artificial re-test reliability) [1;e]		Y	1		3	3		2	3		N/A	3
predictive power of outcome data for known gold standard outcome measure (for the 5 concepts in IDEA-FAST) [1;e]		Y	1		N/A	2		2	2		N/A	3
low/no calibration (or only seldom, if required only rarely and low effort to do so)		Y	3		3	3		2	2		2	3
what validated digital outputs available – e.g., ECG, respiratory rate, etc.?					N/A	2		N/A	2		N/A	3
how the provided digital outputs could map to the 5 concepts of interests of IDEA-FAST (e.g., physical activity, biophysiology, neuropsychological performance, EEG		Y	3						2			
physical activity					3	3		3	3		N/A	N/A
biophysiology					N/A	N/A		N/A	N/A		N/A	N/A
neuropsychological performance					N/A	N/A		N/A	N/A		N/A	N/A
EEG					N/A	N/A					3	3
social parameters					N/A	N/A					N/A	N/A
what "exploratory" (i.e., potential available but not yet validated by the manufacturer) digital outputs are available – e.g., stress-levels, sleep quality indices, "readiness index", ECG, respiratory rate etc?												
How well do these expoloratory digital outputs map to the 5 concepts of interest of IDEA-FAST. [1;e]		Y	1								2	2
TOTAL: Data Quality, Reliability & Analytics			1.875			2.7			2.4			2.7
Data Access, Transparency, and Handling												
good interoperability (Score API for ease-of-developer-use, consistency and stress test) (for algorithm developers) [3;e]		Y	3		2	2		N/A	2		3	3

how the data from the device are extracted or transferred to the IDEA-FAST data management platform? E.g., will the data be stored on the device until the device returned to the researchers? Will the data be uploaded via internet to the SME					N/A	3		N/A	2		3	3
adherence to standards for output/interfacing (Common data format, such as csv, HDF5, HL7, etc.) [3;e]		Y	3		N/A	3		N/A	3		3	3
documented algorithms/data-processing pipeline (no black box) [1;e]		Y	1		N/A	3		N/A	3		N/A	2
connectivity (modern standard, high reliability and adequate throughput) (for		Y	3		N/A	3		N/A	3		3	3
requirements for platform (e.g., does it only run on iphones, or android or some		Y	4		N/A	1		N/A	3		3	3
full raw data access (mandatory binary check) [4;e]		Y	4		N/A	3		N/A	2		3	3
TOTAL: Data Access, Transparency, and Handling			3			2.5			2.6			2.9
Accessibility, Usability and User Experience												
Device comfort (using validated ergonomics) (for end users)	Y	Y	4	3	3	3	3	2	3	1	3	3
Device does not get hot during (typical) use	Y	Y	2		3	3		2	3		3	3
Convenience of wearing device for (typically) required duration	Y		3		3	3		1	2		3	3
Usability (with two further sub-criteria)			4	3	3	3	3	2	3	2	2	2
- Device frustration	Y	Y	4		3	3	2	2	3	1	2	3
- Application frustration	Y	Y	3	2	N/A	2	2	2	3		2	2
User experience (with two further sub-criteria)	Y	Y	2		2	2			2	1	1	2
- Perceived usefulness of the device/application	Y		2	2	2	2		2	2	2	2	2
- Perceived representativeness/trustworthiness of data produced by	Y		2	3	N/A	2		2	2	1	2	2
Ruggedness/robustness of device	Y	Y	2	3	3	3	2	2	3	2	2	3
Connectivity from device to (most likely) phone	Y		3	3	N/A	N/A	2	3	3	1	N/A	3
Hygiene (e.g. how easy is the device to clean? Does it get dirty easily?)	Y	Y	4	3	3	3		2	1		2	2
Device visual acceptability (e.g. is the device visually sympathetic with users'	Y		4	3	3	3	3	2	2	3	3	3
Application visual acceptability	Y		3		N/A	2		2	3	3	3	3
Can device be combined with potential other required devices?		Y	3	3	N/A	2		3	3	3	3	3
Device unobtrusiveness	Y	Y	3	3	3	3		2	2	1	2	1
Application unobtrusiveness	Y	Y	2		N/A	1		3	3	1	2	3
Time required to setup, for health professionals		Y	3	3	3	2		3	3		3	3
User experience of onboarding/setup device ready for use	Y		3	3	3	3	2	3	3	2	2	3

Device for continual use (24/7) or only for specific activities (e.g., sleep)? Does device have to be removed for certain activities (e.g., shower/swim etc.)		Y	4	3	3	3		1	1	1	2	2
Location(s) [on the body or in the room]:		Y	4									
Wrist					3	3						
Hand, finger												
Arm												
Leg, ankle, thigh												
Head, ear								3	3		3	3
Body, chest, abdomen												
Off-body, room, bed												
TOTAL: Accessibility, Usability and User Experience			3.048			2.7			2.4			2.3
Regulatory Concerns												
CE marked [5;e]		Y	5		N/A	3		3	3		3	3
CE mark intended use conformity [4;e]		Y	4		N/A	N/A		N/A	N/A		N/A	N/A
Safety of device use [4;e]		Y	4		N/A	3		1	1		N/A	3
FDA/FCC approval [1;e]		Y	1		N/A	N/A		N/A	N/A		N/A	N/A
GDPR conformity (of potential companion app) [4;e]		Y	4		3	3		3	3		3	3
HIPAA conformity (of potential companion app) [1;e]		Y	1		N/A	N/A		3	3		3	3
instruction manual available in all language of the 11 countries of IDEA-FAST? [1;e] (meta-analysis, not testing … we will need to prepare FAQ sheets + support videos		Y	1		N/A	2		2	2		2	2
TOTAL: Regulatory Concerns			2.857			2.8			2.4			2.8
Scalability												
device battery runtime (if applicable), plus possibility to recharge easily/quickly	Y	Y	4	3	3	3		N/A	3	2	2	3
Application impact on smartphone battery [2;e]		Y	2		N/A	N/A		N/A	3		N/A	1
cost per unit [4;e]		Y	4		N/A	2		N/A	2		N/A	1
Cost for support (also consider cost per user-month or similar to better compare across systems with disposable and noon-disposable elements) [1;e]		Y	1		N/A	2		1	1		1	1
Quality of support and information materials [1;u]	Y		1		N/A	3		3	3		2	2
cost for consumables during use? (e.g., do sensors need to be replaced now and		Y	3		N/A	3		N/A	2		N/A	N/A
reusability [4;e]		Y	4		3	3		3	3		3	3
Cost for reuse [2;e]		Y	2		3	3		1	1		2	1

ease of reuse [2;e]		Y	2		3	3		3	3		3	3
estimated app-adjustment +/ data integration cost [1;e]		Y	1		N/A	2		N/A	1		N/A	2
TOTAL: Scalability			2.4			2.8			2.2			2
Track Record and Data Availability (Mark Van Gills and Jerome Kalifa looking at												
peer-reviewed publications of studies in which the technology has been validated with performance assessment [3;e] (meta-analysis)		Y	3		N/A	3		N/A	2		N/A	3
other publications/material/study data convincingly demonstrating performance in different settings [3;e] (meta-analysis)		Y	3		N/A	3		N/A	2		N/A	3
has the device been validated with healthy volunteers? [1;e]		Y	1		N/A	3		N/A	2		3	3
has the device been validated with the disease populations relevant to IDEA-FAST?		Y	1		N/A	N/A		N/A	N/A		N/A	N/A
has the device been tested in other disease populations? If so are the data		Y	1		N/A	N/A		N/A	N/A		N/A	N/A
TOTAL: Track Record and Data Availability			1.8			3			2			3

IDEA-FAST Device and Application Experience Diary

IDEA-FAST project members or study participants can use this form to provide loosely structured feedback on the experience, acceptability, usability, ergonomics, accessibility, etc. of the candidate devices and applications.
Version 1.0

* Required

1. Name or participant code of reporting person: *

Enter your answer

2. Affiliation of reporting person (if not study participant):

Enter your answer

3. Email address of reporting person (if not study participant):

Enter your answer

4. Device or application reported on: *

Select your answer

5. Other devices and/or applications used in parallel:

Enter your answer

6. Report file date: *

usually current date unless transferring existing report

Please input date in format of dd/MM/yyyy

7. Reporting on period starting from: *

Please input date in format of dd/MM/yyyy

8. Reporting on period lasting until: *

Please input date in format of dd/MM/yyyy

9. Reporting series code name:

if applicable

Enter your answer

10. Reporting series start date:

if applicable

Please input date in format of dd/MM/yyyy

11. Reporting series end date:

if applicable

Please input date in format of dd/MM/yyyy

12. Describe your experience of using the device and/or application:

Enter your answer

13. Describe any notable technical issues that occurred when using the device and/or application:

Enter your answer

14. Comment on how much time and effort was required to use the device and/or application:

Here, you might want to consider:
- Onboarding/set-up experience;
- Connecting the device to application (phone);
- Battery life and charging;
- Frustrations in using the device and/or application.

Enter your answer

15. Comment on how acceptable it was to use the device and/or application (e.g. how well the device/application fits into everyday life):

Here, you might want to consider:
- Comfort and convenience of wearing the device;
- If the device gets hot during use;
- The visual acceptability and unobtrusiveness of the device and/or application;
- Whether the device and/or application seems useful and produces representative, trustworthy data;

- How rugged/robust the device is;
- How easily the device gets dirty and how easy it is to clean.

Enter your answer

16. Any other comments or remarks?

Enter your answer

Submit

Never give out your password. Report abuse

IDEA-FAST Short Device Experience Questionnaire

IDEA-FAST study participants or event attendees can use this form to provide structured feedback on their experience (acceptability, usability, ergonomics, accessibility, etc.) with candidate technologies.
Version 1.0.
* Required

1. Participant ID or code:

   If applicable. This should have been provided to you when agreeing to participate in the study. Don't know your ID or code? If an experiment conductor is available, please ask them about the correct ID or code. If not, skip this question.

   _____

2. Participant group (if applicable):

   This would have been provided to you when agreeing to participate in the study. If you have not been informed about being member of a participant group, please skip this question. Don't remember your group? If an experiment conductor is available, please ask them about your group. If not, skip this question.

   _____

3. Age

   _____

4. Gender:

   Mark only one oval.

   - ◯ Female
   - ◯ Male
   - ◯ Prefer not to say
   - ◯ Other: _____

Quick Device Experience Questionnaire

The questions in this section relate to your use and experience with a technology you tried / tested.

5. Please indicate the name of the technology you are reporting on: *

Check all that apply.

- [ ] Technology A
- [ ] Technology B
- [ ] Technology C
- [ ] Other: _____

6. Location of the technology:

If the technology is a wearable: please indicate the body location that you've primarily worn it on for the reporting period. If the device is a stationary non-wearable device, please indicate where it was primarily located for the reporting period.

Mark only one oval.

- ◯ the technology is a software application (e.g. smartphone app)
- ◯ technology not worn on body (located in bed)
- ◯ technology not worn on body (located elsewhere in room or environment)
- ◯ head
- ◯ ear
- ◯ neck
- ◯ shoulder
- ◯ upper arm
- ◯ lower arm
- ◯ wrist
- ◯ hand
- ◯ finger
- ◯ chest
- ◯ upper back
- ◯ lower back
- ◯ stomach
- ◯ hips
- ◯ upper leg
- ◯ knee
- ◯ lower leg
- ◯ ankle
- ◯ foot
- ◯ other wearable location
- ◯ other stationary device location
- ◯ none of the above

7. Other devices and/or applications used in parallel:

   If you are reporting on a device and have used another device - or multiple devices - and an app - or multiple apps - together with that device (i.e. at the same time), please name it - or them - here.

8. For how many minutes did you use the technology (in total)?

9. Please indicate how far you agree with the following statements about your experience with the technology:

Quick intuitive answers are best.

Mark only one oval per row.

	1 (disagree)	2	3	4	5 (agree)	I can't say or doesn't apply
I found the technology easy to set up (e.g. place or put on) and start using.						
I found the technology comfortable to wear (or use).						
I found using the technology to be an enjoyable experience.						
I found using the technology to be an interesting experience.						
I could imagine wearing or using the technology continuously in the daytime.						
I could imagine wearing or using the technology continuously in the nighttime.						
I found the technology to be pleasant to the touch (if applicable).						
I found the technology visually appealing.						
Using the technology was a burden for me.						
I think the visual appearance of the technology may be						

problematic for everyday use.						
I found it frustrating to use the technology.						
(If you used the technology in parallel with other devices) I found the combination using the devices at the same time to be problematic.						
(If the technology makes use of audio signals) I found the audio signals to be helpful.						
I think the technology is rugged and robust (doesn't break easily).						

10. I would summarise my experience with the technology as... *

Mark only one oval.

	1	2	3	4	5	6	7	
negative								positive

11. If you used an app or an app together with a device: Trustworthiness of Content

In my opinion, the information and data provided by the application are

Mark only one oval.

	1	2	3	4	5	
useless						useful

12. If you used an app or I used an app together with a device: Trustworthiness of Content

In my opinion, the information and data provided by the application are

Mark only one oval.

	1	2	3	4	5	
untrustworthy	◯	◯	◯	◯	◯	trustworthy

13. If you used an app or I used an app together with a device: Trustworthiness of Content

In my opinion, the information and data provided by the application are

Mark only one oval.

	1	2	3	4	5	
inaccurate	◯	◯	◯	◯	◯	accurate

14. If you experienced any technical problems or errors when using the technology, please enter them here:

_____

15. If you have any further short comments about your experience with the technology, please enter them here.

_____

IDEA-FAST Device and Application Experience Questionnaire

IDEA-FAST project members or study participants can use this form to provide structured feedback on their experience (acceptability, usability, ergonomics, accessibility, etc.) with candidate devices and applications.

Some sections of the form are optional (noted within the form) so that brief responses can be given if time is short.

Version 1.0
* Required

1. Age:

_____

2. Gender:

Mark only one oval.

- ◯ Female
- ◯ Male
- ◯ Prefer not to say
- ◯ Other: _____

Participant Information

3. Participant ID or code:

If applicable. This should have been provided to you when agreeing to participate in the study. Don't know your ID or code? If an experiment conductor is available, please ask them about the correct ID or code. If not, skip this question.

_____

4. Participant group (if applicable):

This would have been provided to you when agreeing to participate in the study. If you have not been informed about being member of a participant group, please skip this question. Don't remember your group? If an experiment conductor is available, please ask them about your group. If not, skip this question.

Report Time-Frame...

5. Report series name or ID (if applicable):

If this report belongs to a series of multiple linked reports you are filing, please indicate the name or ID of the series here.

6. Are you reporting on an experience you have made today or some other time? *

Mark only one oval.

- I am reporting on an experience I have made today. *Skip to question 10*
- I am reporting on an experience I have made some other time. *Skip to question 7*

Report Time-Frame, Part 2

7. Original report filing date:

This is usually the current date unless you are transferring an already existing report to this form.

Example: January 7, 2019

8. Reporting on period starting from:

Example: January 7, 2019

9. Reporting on period lasting until:

Example: January 7, 2019

Reporting on a Device?

10. Are you reporting your experience with a device (e.g. wearable or stationary)?

Mark only one oval.

- ◯ Yes, I am reporting on my experience with a device (following your report on the device you will also have the option to report on your experience with a linked application). *Skip to question 11*
- ◯ No, I am not reporting on my experience with a device (you will still have the option to report on your experience with an application in the next step). *Skip to question 24*

Quick Device Experience Questionnaire

The questions in this section relate to your use and experience with a HARDWARE DEVICE ONLY. After this section you will be given the opportunity to also comment on your experience with any software / app that you may have used together with the device.

11. Please indicate the name of the device you are reporting on: *

Mark only one oval.

- ◯ Device A
- ◯ Device B
- ◯ Device C
- ◯ Other: _____

12. Location of the device:

If the device is a wearable: please indicate the body location that you've primarily worn it on for the reporting period. If the device is a stationary non-wearable device, please indicate where it was primarily located for the reporting period.

Mark only one oval.

- ◯ device not worn on body (located in bed)
- ◯ device not worn on body (located elsewhere in room or environment)
- ◯ head
- ◯ ear
- ◯ neck
- ◯ shoulder
- ◯ upper arm
- ◯ lower arm
- ◯ wrist
- ◯ hand
- ◯ finger
- ◯ chest
- ◯ upper back
- ◯ lower back
- ◯ stomach
- ◯ hips
- ◯ upper leg
- ◯ knee
- ◯ lower leg
- ◯ ankle
- ◯ foot
- ◯ other wearable location
- ◯ other stationary device location
- ◯ none of the above

13. Other devices and/or applications used in parallel:

If you are reporting on a device and have used a) another device (or multiple) or b) an app (or multiple) that is intended for other behaviour tracking or for analysis together with that device (i.e. at the same time), please name it - or them - here.

_____

14. Device usage pattern:

Mark only one oval.

- ◯ I have used the device at all times (with interruptions of less than an hour per day).
- ◯ I have used the device for most of my awake hours only.
- ◯ I have used the device for most of my sleeping hours only.
- ◯ Other: _____

15. Please indicate in how far you agree with the following statements about your experience with the device:

Quick intuitive answers are best.

Mark only one oval per row.

	1 (disagree)	2	3	4	5 (agree)	I can't say or doesn't apply
I found the device easy to set up (e.g. place or put on) and start using.	◯	◯	◯	◯	◯	◯
I found the device comfortable to wear (or use).	◯	◯	◯	◯	◯	◯
I found the device to be convenient to put on and remove in regular use.	◯	◯	◯	◯	◯	◯
Using the device was a burden for me.	◯	◯	◯	◯	◯	◯
I found it frustrating to use the device.	◯	◯	◯	◯	◯	◯
I found using the device to be an enjoyable experience.	◯	◯	◯	◯	◯	◯
I found using the device to be an interesting experience.	◯	◯	◯	◯	◯	◯
I found the device to be pleasant to the touch.	◯	◯	◯	◯	◯	◯
I think the device is rugged and robust (does not break easily).	◯	◯	◯	◯	◯	◯
The device easily gets dirty or messy.	◯	◯	◯	◯	◯	◯
The device is easy to clean.	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯

I find the visual appearance of the device to be nice.						
I think the visual appearance of the device may be problematic for everyday use.						
If you used the device in parallel with other devices: I found the combination using the devices at the same time to be problematic.						
I was able to perform my daily tasks as usual while wearing or using the device.						
I could imagine wearing or using the device continuously in the daytime.						
I could imagine wearing or using the device continuously in the nighttime.						
If the device makes use of audio signals: I find the audio signals to be helpful.						

16. I would summarise my experience with the device as... *

Mark only one oval.

	1	2	3	4	5	6	7	
negative								positive

17. If you experienced any noteworthy technical problems or errors when using the device, please indicate them here (briefly):

If you are planning to leave a more complete report, you will be given an option to do so later.

_____

18. If you have any further short comments about your experience with the device, please leave them here.

If you are planning to leave a more complete report, you will be given an option to do so later.

_____

Further Device Reporting?

19. Please indicate whether you would like to complete further questions on the device below:

Mark only one oval.

- ◯ No, I have been told to complete the quick questionnaire only.
  Skip to question 23
- ◯ No, I do not want to answer further questions on my experience with the device.
  Skip to question 23
- ◯ Yes, I would like to provide further details on my experience with using the device.
  Skip to question 20

Detailed Device Experience Questionnaire

20. System Usability Scale (Device)

Please indicate in how far you agree with the following statements:

Mark only one oval per row.

	1 (strongly disagree)	2	3	4	5 (strongly agree)
I think that I would like to use this device frequently.					
I found the device unnecessarily complex.					
I thought the device was easy to use.					
I think that I would need the support of a technical person to be able to use this device.					
I found the various functions in this device were well integrated.					
I thought there was too much inconsistency in this device.					
I would imagine that most people would learn to use this device very quickly.					
I found the device very cumbersome to use.					
I felt very confident using the device.					
I needed to learn a lot of things before I could get going with this device.					

21. Accuracy of Data

In my opinion, the information and data captured by the device are

Mark only one oval.

	1	2	3	4	5	6	7	
inaccurate	◯	◯	◯	◯	◯	◯	◯	accurate

22. Frustration

How insecure, discouraged, irritated, stressed, and annoyed were you due to using the device?

Mark only one oval.

	1	2	3	4	5	6	7	8	9	10	
very low	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	very high

Reporting on an Application?

23. Are you reporting your experience with an application (e.g. a smartphone app)?

Mark only one oval.

◯ Yes, I am reporting on my experience with an application (either together with or without using a linked device). *Skip to question 24*

◯ No, I am not reporting on my experience with an application. *Skip to question 39*

Quick Application Report

24. Please indicate the name of the application you are reporting on: *

Mark only one oval.

- App A
- App B
- App C
- Other: _____

25. Device the application was running on:

Mark only one oval.

- Smartphone (Android)
- Smartphone (Apple)
- Tablet (Android)
- Tablet (Apple)
- Computer (Windows or Linux)
- Computer (iOS)
- Other: _____

26. Was the application running on your personal device?

Mark only one oval.

- Yes, the application was running on my personal device.
- No, the application was running on a device that was provided to me.

27. Device or devices used with the application:

If you are reporting on an application and have used it together with a linked or paired device (or multiple devices), please name it - or them - here.

_____

28. Application usage pattern:

Mark only one oval.

- ◯ I used the application multiple times per day.
- ◯ I used the application multiple times per week.
- ◯ I used the application multiple times per month.
- ◯ I have only used the application once.
- ◯ Other: _____

29. Please indicate in how far you agree with the following statements about your experience with the application (app):

Quick intuitive answers are best.

Mark only one oval per row.

	1 (disagree)	2	3	4	5 (agree)	I can't say or doesn't apply
I found the app easy to set up and start using.						
Using the app was a burden for me.						
I found it frustrating to use the app.						
I found using the app to be an enjoyable experience.						
I found using the app to be an interesting experience.						
I think the app is stable and robust (does not crash easily).						
The functions of the app are clear and easy to understand.						
I find the visual appearance of the app to be nice.						
I could imagine using the app frequently.						
If the app makes use of audio signals: I find the audio signals to be helpful.						
If the app makes use of audio signals: I find the						

audio signals to be annoying.

30. I would summarise my experience with the application as... *

Mark only one oval.

	1	2	3	4	5	6	7	
negative	◯	◯	◯	◯	◯	◯	◯	positive

31. If you experienced any noteworthy technical problems or errors when using the application, please indicate them here (briefly):

If you are planning to leave a more complete report, you will be given an option to do so later.

32. If you have any further brief comments about your experience with the application, please leave them here.

If you are planning to leave a more complete report, you will be given an option to do so later.

Further Application Reporting?

33. Please indicate whether you would like to complete further questions on the application below:

Mark only one oval.

- ◯ No, I have been told to complete the quick questionnaire only. *Skip to question 39*
- ◯ No, I do not want to answer further questions on my experience with the application. *Skip to question 39*
- ◯ Yes, I would like to provide further details on my experience with using the application. *Skip to question 34*

Detailed Application Experience Questionnaire

34. System Usability Scale (Application)

Please indicate in how far you agree with the following statements:

Mark only one oval per row.

	1 (strongly disagree)	2	3	4	5 (strongly agree)
I think that I would like to use this application frequently.					
I found the application unnecessarily complex.					
I thought the application was easy to use.					
I think that I would need the support of a technical person to be able to use this application.					
I found the various functions in this application were well integrated.					
I thought there was too much inconsistency in this application.					
I would imagine that most people would learn to use this application very quickly.					
I found the application very cumbersome to use.					
I felt very confident using the application.					
I needed to learn a lot of things before I could get going with this application.					

35. Trust

Regarding the use of my personal information and data, the application is

Mark only one oval.

	1	2	3	4	5	
untrustworthy	◯	◯	◯	◯	◯	trustworthy

36. Usefulness of Content

In my opinion, the information and data provided by the application are

Mark only one oval.

	1	2	3	4	5	
useless	◯	◯	◯	◯	◯	useful

37. Accuracy of Content

In my opinion, the information and data provided by the application are

Mark only one oval.

	1	2	3	4	5	
inaccurate	◯	◯	◯	◯	◯	accurate

38. Frustration

How insecure, discouraged, irritated, stressed, and annoyed were you due to using the application?

Mark only one oval.

	1	2	3	4	5	6	7	8	9	10	
very low	◯	◯	◯	◯	◯	◯	◯	◯	◯	◯	very high

Also File an Experience Diary?

39. Please indicate whether you would also like to complete an experience diary about your use of the device or application (or both together): *

Mark only one oval.

- ◯ No, I have been told to complete the questionnaire(s) only. *Skip to question 44*
- ◯ No, I do not want to complete an experience diary. *Skip to question 44*
- ◯ Yes, I would like to complete an experience diary. *Skip to question 40*

Experience Diary

40. Describe your experience of using the device and/or application:

41. Describe any notable technical issues that occurred when using the device and/or application:

42. Comment on how much time and effort was required to use the device and/or application:

Here, you might want to consider: - Onboarding/set-up experience; - Connecting the device to application (phone); - Battery life and charging; - Frustrations in using the device and/or application.

43. Comment on how acceptable it was to use the device and/or application (e.g. how well the device/application fits into everyday life):

Here, you might want to consider: - Comfort and convenience of wearing the device; - If the device gets hot during use; - The visual acceptability and unobtrusiveness of the device and/or application; - Whether the device and/or application seems useful and produces representative, trustworthy data; - How rugged/robust the device is; - How easily the device gets dirty and how easy it is to clean.

Final Remarks or Comments?

44. If you have any final remarks or comments about your experience with the device and/or application, please leave them here:

45. If you have any comments about this questionnaire, please leave them here:

Pre-Feasibility Study Version

			Data Quality, Reliability & Analytics					
Device Ref.	**Device Name**	**Device Set**	Raw data accuracy (if applicable)	Processed data accurracy (if applicable)	Data consistency (few data gaps) [0.0 - 1.0]	Duration of "daily wearing" required to capture telling data	Frequency of calbriation required	Validated derived measures available – e.g., ECG
Format for data entry >			*Rate 1-5 low-high*	*Rate 1-5 low-high*	*Valid data points / recorded time steps*	*Approximate time (minutes) (day/night/ both/any)*	*Calibrations per day*	*List*

Testing Group Colour Key SITENAME: N experts

											Data Access, T
Exploratory derived measures (i.e. available but not yet	How well do the available digital outputs possibly map to the 5 concepts of interests of IDEA-FAST						Interoperability, i.e. for algorithm developers, for developers	Standards used for output/interfacing (Common data format	Documented algorithms/ data-processing pipeline (no	Ease of connecting to companion device (e.g smartphone	
	Physical activity	Biophysiology	Neuropsychological performance	EEG	Social parameters						Frequency
List	*Rate 1-5 low-high*						*Rate 1-5 low-high*	*List*	*Yes/No (comment)*	*Rate 1-5 easy-hard*	*Daily/ weeky/ every x days*

Transparency, and Handling						Accessibility, U				
Data transfer...		Platform compatibility	Full raw data access			Device comfort for users (expert opinion)	Does device get hot during (typical) use - user discomfort or	Frustration using Device (expert opinion)	Frustration using Application (expert opinion)	User experience (expert opinion)
Through Cloud	Locally (wired, BlueTooth, etc.)		Raw data	Pre-processed data	Derived measures					
yes/no	*yes/no*	*List operating systems*	*Yes/No*			*Rate 1-5 low-high*	*Yes/No*	*Rate 1-5 low-high*	*Rate 1-5 low-high*	*Rate 1-5 low-high*

Usability and User Experience						Regulatory Concerns				
Ruggedness/robustness of device	Hygiene (e.g. how easy is the device to clean? Does it get dirty	Other devices (core group) that can be used in combination	Time required to setup in study setting	Typical usage pattern - is the device for continuousl use (24/7) or	Potential locations on the body, or in a room.	CE mark intended use compatible with study requirements	Safety of device use	GDPR conformity (of potential companion app)	Device battery utility	
									Runtime	Recharging time
Rate 1-5 low-high	*Rate 1-5 low-high*	*list*	*Approximate time (minutes)*	*Continuous OR list [activity names]*	*List*	*Yes/No*	*Rate 1-5 low-high*	*Yes/No/NA*	*Approximate time (hours)*	

Scalability							Miscellaneous	Data Volume
Perceived impact of companion application on smartphone	Estimated effort required for support activities in	Cost for consumables during use (e.g. if sensors need to be	Reusability of device	Ease of reuse	Cost for reuse [2;e]	Effort adjusting and integrating data from device/applica	Any additional comments	Amount of data per user per day
Rate 1-5 low-high	*Rate 1-5 low-high*	*Estimated weekly cost (EUR)*	*Rate 1-5 low-high*	*Rate 1-5 low-high*	*Estimated cost per reuse cycle (EUR)*	*Rate 1-5 low-high*		*MB*