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Atrial Fibrillation Integrated Approach In Frail, Multimorbid, And Polymedicated Older People

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1 Executive Summary

This document contains the high-level requirements that will form the basis of software architecture designs (to be produced as part of D5.5), interactive prototypes (D5.6) and the iABC platform (D5.7). Requirements have been recorded and prioritised using the MoSCoW approach. At this stage in the project the co-morbidities to be included and the specifics of the digital intervention have not yet been defined. The requirements gathered so far are built upon the work undertaken in the mAFA II trial (Guo19) and early input from work packages 2, 3, 4, 5, 6 & 7.

2 Introduction

The high-level requirements document provides a list of requirements that will be used to inform software architecture designs (deliverable D5.5), interactive prototypes (deliverable D5.6) and the iABC platform (deliverable D5.7) to be used in the randomised control trial. At this stage in the project the co-morbidities to be included and the specifics of the intervention are yet to be defined. We can however identify some of the tools likely to be used in the intervention and understand what needs to be included when building the iABC.

The requirements list is built upon the work undertaken in the mAFA II trial (Guo19) and early input from work packages 2, 3, 4, 5, 6 & 7. It is anticipated that new requirements may emerge during the identification of co-morbidities and as the project progresses. We have adopted the MoSCoW approach for prioritising each requirement such that any new emerging requirements can be evaluated relative to the existing set.

UNIMAN designs and develops software using the Agile software development methodology (more specifically, Scrum). Using Scrum with MoSCoW prioritisation allows us to work with high-level requirements to develop a software delivery plan, whilst refining the requirements to be developed first.

3 MoSCoW prioritisation

Each requirement has been classified using the MoSCoW approach and will also be allocated an estimated resource amount which, when combined with the priority of each item, can be used to ensure the iABC platform delivers the highest value requirements. The MoSCoW document will be the source of truth during any requirements discussions and will also be a living document that can be updated as the project progresses.

3.1 Prioritisation

The MoSCoW approach defines each requirement as one of: Must have, Should have, Could have, Won't have.

3.1.1 Must have

These provide the Minimum Usable SubSet (MUST) of requirements which the project guarantees to deliver. These may be classified using at least one of the following:

- If the requirement were not delivered, there would be no point deploying the solution;
- The solution is not legal without it; or
- The solution is unsafe without it.

3.1.2 Should have

Should have requirements can be classified as one of:

- Important, but not vital to the solution;
- May detract from the quality of the solution if excluded, but the solution still works without; or
- A workaround can be put in place that does not require more resource to implement than the requirement itself.

3.1.3 Could have

Could have requirements can be defined as:

- Wanted or desirable, but less important than Should have requirements; or
- Often termed "nice-to-haves".

3.1.4 Won't have

Won't have [this time] requirements are those which the project team has agreed will not be delivered (as part of the current deployment). They are recorded in the high-level requirements document where they help clarify the scope of the project. This avoids them being informally reintroduced later. This also helps to manage expectations that some requirements will simply not make it into the final product, at least not this time around. Won't have requirements can be very powerful in keeping the focus at this point in time on the higher priority items.

3.2 Refining requirements

As AFFIRMO progresses, each high-level requirement will be explored and further defined as a list of low-level requirements. The MoSCoW approach is applied at each level of requirements specification. This method allows the project team to flex the requirements to ensure the resource required and delivery dates remain fixed and is therefore well suited to research projects.

It is expected that a number of the requirements defined here as Should Have requirements will become Must Have requirements as Work Packages 2, 3, 6 & 7 progress, and the details of the intervention emerge.

3.3 Determining software output

When planning delivery of software at the project level, it is expected that all Must Have requirements will be delivered, as well as some Should Have and Could Have requirements (if time permits all requirements not marked as Won't Have may be delivered, although this is unusual). Software will be delivered in increments, to facilitate regular feedback from stakeholders. Each increment should also contain a mix of requirement priorities. The inclusion of only Must Have requirements does not provide the software developer(s) with contingency should any unforeseen problems occur.

4 High-level requirements

The list of high-level requirements and their MoSCoW prioritisation are presented below. Requirements that have been classified as Won't Haves are also included.

Title	Summary	Source	Priority
Prescriptions management	The platform will allow users to manage and view prescriptions. Historical, current, and future prescriptions should be visible both to the patient and the clinical teams. This may also include patient-entered adherence to prescriptions.	mAFA II	Must Have
Role-based access	<p>Ensure role-based access is implemented for data access and display. Roles shall include as a minimum:</p> <ul style="list-style-type: none"> • Patient (intervention arm only) • Interventionist • Researcher (de-identified data view only) • Administrators 	WP5	Must Have
Language translation	The digital platform shall be translated to local language. The languages that we expect to support are: English, Spanish, Danish, Italian, Serbian, Romanian and Bulgarian.	WP1	Must Have
Geriatric usability considerations	<p>The iABC platform shall be built with accommodations for the target user population. This may include items such as colour, language, imagery, buttons, etc. At this point we don't know the co-morbidities that will be included in the RCT with this requirement becoming more specific as WP2&3 progress.</p> <p>Through other work packages we will consider patient group input.</p>	WP1	Must Have

Governance documentation	Ensure clear links to governance documents including but not limited to Data Protection Impact Assessments, Data Sharing Agreements, Data Processing Agreements, Codes of Practice, Standard Operating Rules and Procedures, Data Protection and Transparency / Privacy Notices, Service Level Agreements, IRB / REC Approvals where appropriate, Health Regulatory Approvals documents for each site, scoped risk management (where the DPIA will need to be general and inform local sites), where risk management processes must justify Req 3 particulars.	WP5	Must Have
Education module	<p>The platform shall provide participants with a series of videos, factsheets, and tools to help them manage their lifestyle.</p> <p>This may include diet and exercise information, liver and renal function monitoring plans, different ways to take BP readings, and other items specific to the co-morbidities determined as part of WP2/3.</p>	mAFA II / WP2&3	Must Have
Click analytics / Dashboard	<p>The platform shall include functionality to allow investigators to access information regarding the use of the iABC platform throughout the trial. This could be fortnightly or monthly. The mechanism used to provide this functionality is still to be determined (i.e. we could do this by way of a regular export, or potentially building this into the dashboard).</p> <p>We shall define what it means for a patient to adhere to use of the platform with input from WP6/7. Currently it is suggested that we will simplify the language to categorise adherence as low/medium/high but this needs further investigation.</p> <p>This may also include usage data to understand the areas of high and low use within the platform.</p>	WP6	Must Have

Audit	We need to have a robust audit process to track usage of the app and actions of users. We must always remain accountable and demonstrate compliance with proof of activity, access, data handling and amendment and archiving backed up by logs.	WP5	Must Have
Data downloads	Along with the click analytics and dashboard, WP8 will need access to iABC (de-identified) raw data. We shall provide a method for data access/download based on roles.	WP8	Must Have
Web, mobile and tablet compatibility	The iABC platform shall be compatible with web, tablet and mobile devices. We cannot support all devices due to the enormous array of devices on the market and will base our designs and testing on market research, supporting those devices most commonly used in the target countries. This will include iOS as well as Android-based devices.	WP4	Must Have
Blood pressure monitoring	We shall provide a data capture form allowing users to manually enter blood pressure readings. Data should be visible to appropriate roles.	mAFA II	Must Have
Data sharing control	The participant should be able to control interactions with the app (e.g. turning notifications on/off, data sharing, etc.)	WP5	Should Have
Patient feedback	Allow patients to provide feedback via the iABC. This may take the form of a feedback form on the platform or may be a more formal questionnaire and prompt to periodically source feedback. Any questions will need to be defined in advance. As part of this requirement consideration will also need to be given regarding who should receive any feedback and whether a need for SLAs to respond should exist.	WP9	Should Have

	An alternative approach would allow a user the ability to give a “thumbs up” if they like a particular item/page/piece of information.		
Weight/activity log	Allow patients to diarise their weight, BMI and possibly activity. If available, we may take activity data from a smart device. Based on the work done as part of the mAFA II trial we will also use the physical activity questionnaire (PAQ).	mAFA II	Should Have
Sleep apnea	Taken from subsequent development of the mAFA II app, we shall include data capture forms for sleep apnea screening questionnaires (Berlin Questionnaire), Stop-Bang questionnaire, and Epworth Sleeping Scale (ESS).	mAFA II	Should Have
Clinical decision-making tool	Inclusion of clinical decision support tools based on the work undertaken in the mAFA II trial. Use one or more of CHA2DS2-VASc, HAS-BLED, SAME-TT2R2 to help produce scores and risk strata.	mAFA II	Should Have
Cardiac/Pulse rhythm monitoring	Allow patients and members of the clinical teams to enter cardiac rhythm monitoring data via a data capture form with the data visible in near real-time to both patients and clinical teams. Regular notifications may be used to prompt the user to complete.	mAFA II	Should Have
Localisation	This requirement is similar, yet distinct from simple language translation. Based upon local input, we should customise the way in which users flow through the app and the information they are presented with (e.g. referencing local health systems).	WP6	Should Have

Clinical alert & action system	Using parameters and clinical measurements to be defined, we should provide a dashboard whereby clinicians are notified if a patient's symptoms have changed. This should not replace clinical decision making and should build on the clinical decision rule above. Clinical users can mark items as actioned and provide notes if required.	WP6	Should Have
Dietary support	Support participants regarding dietary choices. This could include a barcode scanner (which would require the use of a 3rd party to provide the data) or a series of informational tools (forming part of the education module). mAFA II used the Alternative Healthy Eating index (AHEI-2010) which could be included as part of the assessment of diet quality.	mAFA II	Could Have
Sleep apnea	We will investigate integration of wearable continuous sleep monitoring if participants have compatible smart phone and devices. The large combination of wearables devices, mobile devices and operating systems presents a barrier to implementation.	mAFA II	Could Have
Blood pressure monitoring	We will investigate potential integration of blood pressure monitoring cuffs for use at-home to facilitate real-time measurement and data transfer. The large combination of wearables devices, mobile devices and operating systems presents a barrier to implementation.	mAFA II	Could Have
Cardiac/Pulse rhythm monitoring	We will investigate potential integration of cardiac/pulse rhythm monitoring for use at-home to facilitate real-time measurement and data transfer. The large combination of wearables devices, mobile devices and operating systems presents a barrier to implementation.	mAFA II	Could Have

	We are also considering the use of patient device camera use for PPG analysis, but this is not certified for medical device use and will need to be further evaluated.		
Daily, weekly and monthly participant checklists	Provide patients with an easy-to-use set of checklists to support adherence. Support with push notifications and items to "tick off".	WP5	Could Have
Guideline based treatment recommendations	Provide clinicians with recommendations for treatment based on guidelines. This will need further defining when co-morbidities are confirmed.	WP2, WP3, WP6, WP7	Could Have
Cardiac age	Show users their cardiac age in 10 years based on risk factors. Allow users to enter risk factors and present their risk over the next 10 years. This will not be included as we would not have the supporting clinical processes in place to support this.	WP5	Won't Have
Healthy Plan	Provide participants with a daily plan for exercise and diet, including any additional data points collected as part of the iABC platform. Prof Guo as part of the lamHealthy project (Guo21) developed a customised daily plan for participants. We have de-scoped this as there is already a significant number of mobile apps out there that offer this functionality. We will include information related to this as part of the education module.	lamHealthy	Won't Have
AI risk prediction	Prediction of AF using machine learning techniques to alert clinical teams of increased risk. We will not be including the use or building of AI as part of AFFIRMO and have therefore de-scoped this requirement.	lamHealthy	Won't Have
Live chat functionality	As part of the mAFA II trial, chat functionality was supported by members of clinical teams supporting patients in their own free time. We will not be	mAFA II	Won't Have

	requesting clinical support on a pro bono basis and therefore will not be including this in the iABC platform.		
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5 Next steps

WP5 will use the requirements detailed above to begin the production of interactive prototypes (D5.6). Visual prototypes allow the wider consortium and end user groups the opportunity to evaluate the understanding of each of the requirements. We (UNIMAN) have found that the use of visual prototypes helps to elicit assumptions and crystallises the areas of most (and least) interest in our proposed platforms.

The requirements listed here will also inform the software requirements specifications, including discussions regarding data security and hosting requirements.

6 Bibliography

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- [Guo21] Guo Y. "Lifestyle modification based on cluster cardiovascular risk assessment reduced the risk of sleep apnea". In press. 2021.