



AFFIRMO_D5.7_Digital platform_21.12.2023_v1.0
Dissemination Level: CO



H2020-SC1-BHC-2018-2020 / H2020-SC1-2020-Two-Stage-RTD

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

Project no.: 899871

Project full title: Atrial Fibrillation Integrated Approach In Frail, Multimorbid, And Polymedicated Older People

Project Acronym: AFFIRMO

Deliverable number:	D5.7
Deliverable title:	Digital platform
Work package:	WP5
Due date of deliverable:	M24 M32
Actual submission date:	M32 - 21/12/2023
Start date of project:	01/05/2021
Duration:	60 months
Reviewer(s):	John Ainsworth (UNIMAN), Sanaullah Alam (UNIMAN)
Author/editor:	Charlotte Stockton-Powdrell (UNIMAN)
Contributing partners:	The European Institute for Innovation through Health Data (i~HD), Aalborg Universitet (AAU), The University of Liverpool (UoL), Universiteit Gent (UGent), Karolinska Institutet (KI), Arrhythmia Alliance (A-A), Istituto Superiore di Sanità (ISS), Heart Care Foundation Onlus (HCF), University of Manchester (UNIMAN).

Dissemination level of this deliverable	PU
Nature of deliverable	Report

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 899871. Any results of this project reflect only this consortium's view, and the European Commission is not responsible for any use that may be made of the information it contains. Further information is available at www.affirmo.eu.

Table of Contents

1	Executive Summary	3
2	Introduction.....	4
3	UNIMAN Software Development Process	5
3.1	Software Development Process (PR-07)	5
3.1.1	Additional processes and collaboration	5
3.1.2	Clinical Contributions	5
3.1.2.1	Technical Contributions.....	5
3.1.2.2	Patient and Public Contributors	6
3.1.2.3	Language Translations	6
3.1.2.4	Empowerment Materials.....	7
3.1.2.5	Testing and Feedback	7
3.1.2.6	App Store Releases	8
4	Conclusions and Outlook.....	9
5	Bibliography.....	10
6	Annex A	11

List of Figures

Figure 1: Software Development Process	5
--	---

List of Tables

Table 1: Outputs from PPIE Workshop.....	6
Table 2: Pen testing issues	7

VERSION AND AMENDMENT HISTORY

Version	Date (DD/MM/YYYY)	Created/Amended by	Changes
V0.1	11/12/2023	Charlotte Stockton-Powdrell	First version: Skeleton report
V0.2	13/12/2023	Charlotte Stockton-Powdrell	Updated with partners' input
V0.3	15/12/2023	Sanallah Alam	First review of the full document
V0.4	18/12/2023	Charlotte Stockton-Powdrell	Updated with input from the first review
V0.5	19/12/2023	John Ainsworth	Second review of the full document
V0.6	19/12/2023	Charlotte Stockton-Powdrell	Updated with input from the second review
V0.9	20/12/2023	Berit Hvidberg Christensen	Proofreading and layout check
V1.0	21/12/2023	Berit Hvidberg Christensen	Submitted to EU Portal

1 Executive Summary

This document describes the process of developing and delivering the AFFIRMO Study app (iABC), formerly known as the iABC digital platform. The initial stages of developing a digital tool that is followed by UNIMAN include the already completed deliverables of D5.1 (High-level requirements document), D5.5 (Software Architecture Designs) and D5.6 (Prototypes). The requirements were gathered from consortium members and prioritised according to the MoSCoW approach described below.

2 Introduction

The high-level requirements document provided an initial list of requirements that were used to inform software architecture designs (deliverable D5.5), interactive prototypes (deliverable D5.6) and the AFFIRMO Study App (iABC) (deliverable D5.7) which will be used in the randomised control trial.

The requirements list was built upon the work undertaken in the mAFA II trial (Guo19) and early input from work packages 2, 3, 4, 5, 6 & 7. New requirements emerged during the identification of co-morbidities and as the project progressed. We adopted the MoSCoW (**M**ust have, **S**hould have, **C**ould have, **W**on't have) approach for prioritising each requirement such that any new emerging requirements were evaluated relative to the initial 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.

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

3 UNIMAN Software Development Process

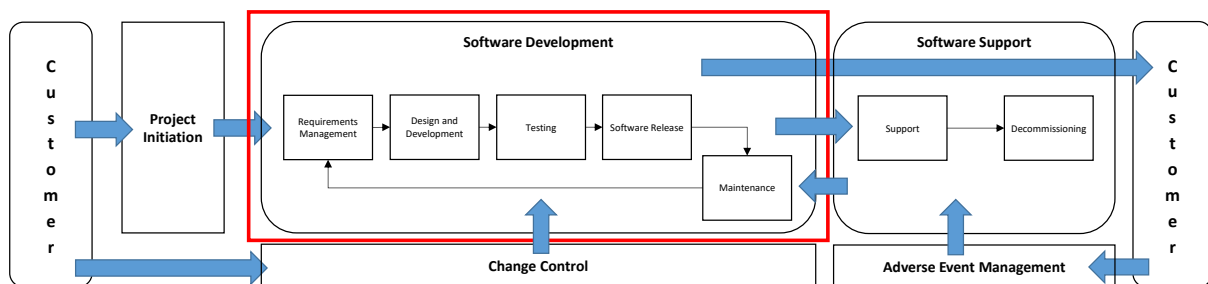
At UNIMAN, we follow a series of software development processes that we have created as part of our internal quality management system (QMS). This is our way of ensuring that we deliver high-quality software by following the same process for each product we develop in a transparent and consistent manner.

3.1 Software Development Process (PR-07)

The UNIMAN Software Development Process (internal document ID PR-07) includes all these phases, as can be seen within the red box in the figure below:

- Requirements Capture
- Design and Development
- Testing
- Software Release
- Software Maintenance

Figure 1: Software Development Process



3.1.1 Additional processes and collaboration

In addition to the phases above, the development of the AFFIRMO Study App (iABC) and its interface with the electronic case report form (eCRF) has been a collaborative effort with other members of the consortium, most specifically Marco Gorini, Marco Proietti and Donata Lucci (WP6) and Guendalina Graffigna and Caterina Bosio (WP9).

3.1.2 Clinical Contributions

It is crucial to ensure that the software we develop is clinically accurate and appropriate. Marco Proietti has provided critical clinical input and advice during the development of the AFFIRMO Study App (iABC). He has helped with the development of items and their flow throughout the app so that the participant journey makes sense practically and clinically.

3.1.2.1 Technical Contributions

Marco Gorini has been instrumental in the development of the electronic case report form (eCRF) hosted by the Heart Care Foundation in Italy. Marco has supported the interface between the eCRF and the

AFFIRMO Study App (iABC) and enabled the thorough testing to be conducted with test patients, to ensure that the system is working effectively prior to recruiting live participants in early 2024.

3.1.2.2 Patient and Public Contributors

We follow a user-centred design approach to our software development, which means we include and involve end users, most often patients or clinicians, in the design and development of our software. In the case of the AFFIRMO Study App (iABC), we worked with the Arrhythmia Alliance to conduct two patient and public involvement and engagement (PPIE) workshops with people who have lived experience of atrial fibrillation. During the workshops, we asked participants to help shape the contents of the app, and the usability of it. In the second workshop, we shared the designs and prototypes of the app (D5.6) and asked people to feedback on how easy or difficult they felt it would be to use the AFFIRMO Study App (iABC). The table below shows the key messages from the workshop.

Table 1: Outputs from PPIE Workshop

General Questions about using the app	
<p>“I think this app looks easy to use.”</p> <p>How much do you agree with the above statement?</p>	<p><input type="radio"/> Agree</p> <p><input type="radio"/> Somewhat agree.</p> <p><input type="radio"/> Neutral</p> <p><input type="radio"/> Somewhat disagree.</p> <p><input type="radio"/> Disagree</p>
<p>“I would imagine that most people would learn to use this app very quickly.”</p> <p>How much do you agree with the above statement?</p>	<p><input type="radio"/> Agree</p> <p><input type="radio"/> Somewhat agree.</p> <p><input type="radio"/> Neutral</p> <p><input type="radio"/> Somewhat disagree.</p> <p><input type="radio"/> Disagree</p>
<p>“I think I would need the support of a technical person to be able to use this app.”</p> <p>How much do you agree with the above statement?</p>	<p><input type="radio"/> Agree</p> <p><input type="radio"/> Somewhat agree.</p> <p><input type="radio"/> Neutral</p> <p><input type="radio"/> Somewhat disagree.</p> <p><input type="radio"/> Disagree</p>

3.1.2.3 Language translations

The AFFIRMO Study App (iABC) was developed in English as this is the official language of the consortium and is also the language of the software team at UNIMAN. The app will be used in six different recruiting countries and, therefore, needs to be available in those six languages: Danish, Spanish, Italian, Serbian, Bulgarian and Romanian.

Each item within the app was translated using Google Translate, and subsequently, the NCC Leads from each country reviewed and corrected the translations of each item within the app. This was further reviewed once the functionality of the app had been tested and verified.

3.1.2.4 Empowerment materials

The empowerment materials were provided by Guendalina Graffigna and Caterina Bosio from WP9 in collaboration with Trudie Lobban from the Arrhythmia Alliance. The materials were translated into each of the six languages as mentioned in 3.1.2.3 above and were provided as .pdf documents to be uploaded into the app and made available as appropriate for participants using the AFFIRMO Study App (iABC).

3.1.2.5 Testing and Feedback

Penetration (Pen) Testing:

We have completed the pen testing for the following elements of the applications to ensure we have developed a secure system:

- AWS Config
- AWS Firewalls
- Web and Mobile APIs
- Web Interface
- APK (Android application)
- iOS (iPhone application)

Below is a summary of the pen testing issues, which will require approximately two weeks to address the high and medium priority points:

Table 2: Pen testing issues

Element	Issues (High)	Issues (Medium)
AWS Config:	1	4
AWS Firewall:	0	0
APK:	0	3
iOS:	0	0
Web:	0	1
APIs:	1	1

Functional Testing and Full System Testing:

We have completed the functional testing for the system. Further rounds of testing are being conducted after incorporating the feedback from Marco Proietti and Guendalina Graffigna.

Integration testing with eCRF has been performed on both the Development and Production environments. Participants added on the eCRF can now be incorporated into the AFFIRMO Study App (iABC). Once added to the iABC Clinician Platform, participants can access the mobile app.

Information Governance Risk Review (IGRR) Review:

We are currently finalising the IGRR review, an information governance and security process required by UNIMAN for all software research projects. This process is anticipated to conclude in January 2024.

3.1.2.6 App Store releases

In order to make the AFFIRMO Study App (iABC) available for participants to download, we released it to both the Apple App Store (for iOS) and Google Play Store (for Android). This is a detailed process that has to go through UNIMAN's Research IT team, and it means we need to align with the criteria required by both Apple and Google in order to make the apps available in the stores.

4 Conclusions and Outlook

Developing a digital application and platform can be a complex process. When doing so with a 20-partner consortium, the process is understandably more complex, not least in terms of trying to reach a consensus on what can be delivered in a meaningful and useful way within the time and funding constraints of a funded research project. Integrating digital platforms that have been created by other teams in other countries adds further complexity to the process.

Despite these additional challenges, we have been able to work successfully with our consortium partners to reach a consensus about the requirements and deliverables for WP5, and we have delivered a functioning mobile application available in seven different languages on both Android and iOS operating systems. This has been a challenging and very rewarding milestone to have achieved.

5 Bibliography

- [Guo19] Guo Y, Lane DA, Wang L, Chen Y, Lip GYH, investigators mAF-App IIT, Eckstein J, Thomas GN, Mei F, Xuejun L. "Mobile Health (mHealth) technology for improved screening, patient involvement and optimising integrated care in atrial fibrillation: The mAFA (mAF-App) II randomised trial". *Int J Clin Pract.* 2019; e13352.

6 Annex A

None.