



STRATIFYHF
Artificial intelligence-based decision support system for risk stratification and early detection of heart failure in primary and secondary care

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D 1.4 – Midterm recruitment report	
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D1.4 – Midterm recruitment report

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Executive summary

Heart failure (HF) is a pandemic currently affecting up to 15 million people in Europe and 64 million people globally^{1,2}. It is a complex clinical syndrome characterised by impaired heart function and associated with poor quality of life for patients and high healthcare costs². The combination of HF being associated with older age, and an increasingly ageing population has led to HF being increasingly challenging to public health³. In addition, the development of multiple long-term conditions (i.e., multimorbidity) occurs over time⁴.

There is a high clinical demand for novel artificial intelligence (AI) tools which will facilitate risk stratification, early diagnosis, and prediction of disease progression in HF. Such tools are essential to allow prompt initiation of evidence-based prevention and treatment strategies, ultimately improving patients' quality of life, reducing morbidity and mortality, and alleviating the burden of HF on healthcare systems.

STRATIFYHF aims to develop, clinically validate, and implement an advanced Decision Support System (DSS) powered by AI and computational modelling to improve the prediction, early diagnosis, and monitoring of HF. This system will integrate a wide spectrum of patient-specific data: including demographic, clinical, genetic, biological, pharmacological, and imaging parameters to optimise therapeutic strategies. The goal is to enhance treatment efficacy, minimise adverse outcomes, prevent sudden cardiac death, and reduce the time to clinical improvement following pharmacological intervention. In parallel, a patient-facing mobile application will be developed to support self-management and enable healthcare professionals to make evidence-based decisions in HF prevention and treatment.

STRATIFYHF is expected to significantly improve diagnostic accuracy and clinical outcomes in HF, while contributing to the efficiency and sustainability of healthcare systems. This includes reducing HF-related hospitalisations and unnecessary referrals from primary to secondary care across Europe and beyond ultimately improving both the quality and longevity of patients' lives.

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List of Abbreviations

Abbreviation	Explanation
COVU	Coventry University, UK
FoMUNS	Faculty of Medicine, University of Novi Sad
HF	Heart failure
HFpEF	Heart failure with preserved ejection fraction
HFmrEF	Heart failure with mid-range ejection fraction
HFrEF	Heart failure with reduced ejection fraction
NA	Not applicable
SERMAS	Servicio Madrileño de Salud – University Hospital Ramon y Cajal
UCAM	University of Cambridge, UK
UMCU	University Medical Centre Utrecht
UNEW	Newcastle University, UK
UNIFI	University of Florence
UHREG	University Hospital Regensburg

1. Introduction

The present document constitutes the midterm recruitment report (Month 18), Deliverable 1.4. This report summarises STRATIFYHF clinical study participant recruitment, and heart failure (HF) classification across the eight clinical centres involved in the study from inception to 31st October 2025.

2. Recruitment Summary Report

2.1 Overall Recruitment

A total of 297 participants were recruited across all centres. Gender distribution shows a predominance of male participants, with 212 males (71%) and 85 females (29%).

Table 1. Recruitment summary as at 31/10/2025

Centre Name	Total (N)	Male (N)	Female (N)	Suspected (HF) (N)	Confirmed (N)		
					HFpEF	HFmrEF	HFrEF
FoMUNS - Novi Sad	44	35 (79%)	9 (21%)	NA	6	13	25
UMCU - Utrecht	65	37 (57)	28 (43)	16	21	6	6
UHREG - Regensburg	67	56 (84%)	11 (16%)	NA	31	23	13
COVU - Coventry	43	28 (65%)	15 (35%)	30	6	1	6
UNEW - Newcastle	27	17 (63%)	10 (37%)	6	7	3	11
SERMAS - Madrid	19	15 (79%)	4 (21%)	NA	9	7	3
UNIFI - Florence	32	24 (75%)	8 (25%)	NA	1	1	30
UCAM - Cambridge	0	-	-	-	-	-	-

2.2 Observations

Heart failure with reduced ejection fraction (HFrEF) was the most frequently confirmed HF subtype across several centres, particularly in Florence and Novi Sad. In contrast, heart failure with preserved ejection fraction (HFpEF) was notably more prevalent in UHREG (Regensburg) and UMCU (Utrecht). Recruitment numbers and HF subtype distribution vary significantly across sites, reflecting potential regional or methodological differences. The absence of recruitment data from UCAM (Cambridge) at the midterm point of the study is a notable observation. UCAM has encountered operational and administrative delays in initiating study activities such as staff onboarding and data infrastructure setup.

3. Conclusion

At the midpoint of the study, recruitment stands at 297 participants, representing less than 20% of the target sample size of 1,600. While most centres have made steady progress, the overall pace of recruitment is significantly behind schedule. Notably, UCAM has yet to contribute any data, reflecting site-specific challenges. Strategic engagement with underperforming sites and reinforcement of recruitment efforts have been initiated to ensure the study meets its objectives within the planned timeline.

4. Deviation from the work plan

There has been no deviation from the work plan. However, we note that there was significant delay to the overall clinical study initiation across all sites beyond the planned start date. Most centres are now surpassing the planned monthly recruitment targets.

5. References

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