Salutare One Referral for MDTs

Single cohort before and after mixed-methods prospective study to investigate the impact of the Salutare One Referral software on patient outcomes, safety and effectiveness of Multi-Disciplinary Team (MDT) meetings

PROTOCOL

Version 2 (22/01/2025)

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1. Summary of Study Design

Title	Single cohort before and after mixed-methods prospective study to investigate the impact of the Salutare One Referral software on patient outcomes, safety and effectiveness of Multi-Disciplinary Team (MDT) meetings
Short Title/acronym	Salutare One Referral for MDTs
IRAS number	347710
Sponsor	Salutare Group Ltd.
Funder name & reference	Salutare Group Ltd.
Clinicaltrials.gov no	TBC
Design	A mixed-methods prospective Before and After Study
Primary objective	The primary objective is to evaluate safety, acceptability and implementation feasibility of the Salutare One Referral Software
Secondary objectives	Determination of the following metrics with and without the use of the Salutare One Referral software: (1) MDT administration time (2) Completeness of pre-assessment information (3) Clinical engagement (4) Time spent by MDT panel members attending meetings (5) MDT performance rating (6) Duration of MDT per-patient discussion time (7) Overall time for MDT meetings (8) Time from referral submission to the generation of MDT definitive decisions. (9) Time from referral submission to the implementation of MDT recommendations (OPTIONAL) (10) Number and rate of cases re-presented for MDT review – breast cancer only (11) Drug changes to accommodate surgery or any disease optimisation advice (12) Presence or absence of peri-operative and post-operative complications (OPTIONAL)
Primary endpoint	The study aims to assess the Salutare One Referral Software's safety, implementation feasibility and users acceptability in facilitating effective MDT meetings. System Usability Score (SUS) and user questionnaires will be administered to MDT panel members, with modifications to the SUS as necessary. The primary and secondary endpoints of the study will inform future

<table>
<tr><td></td><td>protocol amendments and expansion to additional sites. This will enable the selection of suitable endpoints most relevant to the patient pathway and care outcomes, such as the “time from referral to recommendation implementation”.</td></tr>
<tr><td>Secondary endpoints</td><td>
<table>
<tr><th>Measure</th><th>Assessed via</th></tr>
<tr><td>(1) MDT administration time</td><td>Participant questionnaire
MDT meetings observation dataset</td></tr>
<tr><td>(2) Completeness of pre-assessment information
• Medical history Risk score completion
• TNM recording (radiological and pathological) - breast cancer only</td><td>Participant questionnaire
MDT meetings observation dataset
Note: If access to the patient’s medical record is required, for example if any aspects of the pre-assessment information are missing in the forms, the data would be provided by a member of the direct care team.</td></tr>
<tr><td>(3) Clinical engagement</td><td>Participant questionnaire
MDT meetings observation dataset</td></tr>
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MDT meetings observation dataset</td></tr>
<tr><td>(8) Time from referral to the generation of MDT recommendation</td><td>MDT meetings observation dataset
Note: If access to the patient’s medical record is require, for example if the MDT recommendation date is not clear in the forms, the data would be provided by a member of the direct care team.</td></tr>
<tr><td>(9) Time from referral to the implementation of MDT recommendations (OPTIONAL)
• “Decision to Treat” (cancer MDT)
• Date of operation (Anaesthetics)</td><td>MDT meetings observation dataset
Participant questionnaire
Note: If access to the patient’s medical record is required, for example if any aspects of the pre-assessment information are missing in the forms, the data would be provided by a member of the direct care team.</td></tr>
<tr><td>(10) Number and rate of cases re-presented for MDT review – breast cancer only</td><td>MDT meetings observation dataset</td></tr>
</table>
</td></tr>
</table>

	(11) Drug changes to accommodate surgery or any disease optimisation advice.	MDT meetings observation dataset
	(12) Presence or absence of peri-operative and immediate post-operative complications (OPTIONAL)	Medical records to be reviewed by a member of the NHS direct care team
Target	RNOH Anaesthetic MDT: Approximately 20 staff taking part in MDT meeting taking part in the MDT meeting preparation and discussion. We aim to collect data for approximately 40 cases discussed without the Salutare One Referral software and approximately 40 patients discussed with Salutare One Referral. Royal Free (Colorectal Cancer): Approximately 20 staff taking part in MDT meeting taking part in the MDT meeting preparation and discussion. We aim to collect data for approximately 120 cases discussed without the Salutare One Referral software and approximately 120 cases discussed with Salutare One Referral. Royal Free (Breast Cancer): Approximately 50 staff taking part in the MDT meeting preparation and discussion. We aim to collect data for approximately 150 cases discussed without the Salutare One Referral software and 150 patients discussed with Salutare One Referral. (Note: The Royal Free Breast Cancer MDT testing is currently on hold, subject further discussions).	
Inclusion criteria (Active Study Group)	MDT meeting Panel Members, Coordinators and staff submitting MDT referrals will take part in this study.	
Exclusion criteria (Main study)	MDT meeting Panel Members, Coordinators and staff submitting MDT referrals who are unwilling or unable to take part in the study.	
Duration of study	The study consists of 4 phases: 1. Pre-intervention period (before-study control) with no access to the Salutare One Referral software. 2. Onboarding period to allow for software installation and staff training and adjustment to the technology 3. Salutare One Referral intervention period 4. Post-intervention period (after-study control) with no access to the Salutare One Referral software The total duration of the study will depend on the frequency of MDT meetings and the number of cases discussed.	

	• Stanmore Anaesthetics MDT and Royal Free Colorectal Cancer MDT: The study duration will be approximately 18 weeks (4-week pre-intervention period, 2-week onboarding period, 8-week intervention period, 4-week post-intervention period) • Royal Free Breast Cancer MDT: The study duration will be approximately 10 weeks (2-week pre-intervention period, 2-week onboarding period, 4-week intervention period, and a 2-week post-intervention period). Additionally, 4 weeks are allowed to complete the study data collection.
Definition of the start of the study	Following the issue of the HRA approval and the Trust Capacity & Capability approval, the study data collection with start by distributing surveys to the MDT panel members.
Definition of end of study	The study will end when the last study participant returns the last study questionnaire.

2. Background and rationale

2.1. Salutare One Referral

The One Referral product from Salutare Group Ltd is a cloud-based, patient-centred multi-disciplinary team (MDT) meeting application designed to facilitate, standardise and partially automate the referral and review of patient cases. Salutare Group Ltd is a UK-based software company.

The primary objective of One Referral is to simplify and standardize the referral process to hospital or community-based MDTs, aiming to enhance patient safety, efficiency, and the effectiveness of MDT discussions. It achieves this by providing all panel members with essential information necessary for discussing and contributing to MDT clinical decision-making, thereby replacing paper or email-based referrals with a fail-safe system that enables tracking of patient pathways.

Moreover, One Referral facilitates and partially automates the uploading of patient medical history, including laboratory and radiology examinations, distributing this information to MDT panel members. Additionally, One Referral has the capability to access the Summary Care Record via the Spine.

The platform features a comprehensive dashboard that provides a summary of MDT review outcomes and recommendations/actions, such as requests for further medical information. Completed and reviewed referrals can be exported as PDF documents, which are compatible with Electronic Patient Record (EPR) systems.

Future plans for One Referral include the development of a patient engagement module. This module will enable the collection of patient feedback and background clinical data, while also keeping patients informed about the progress and outcomes of MDT reviews.

3. The problem

MDTs aim to improve treatment standards by ensuring that all patients receive considered and homogeneous treatment and care from appropriately skilled professionals. MDTs are widely used in the UK health sector and recognised at a policy level as the preferred means of delivering complex care for chronic as well as acute diseases (Chinai et al., 2013; Maharaj et al., 2021; Raine et al., 2014). The widespread implementation of MDTs in the UK dates back to the early 1990s when the MDT model was recommended as a standard model to improve cancer care, following the publication of the EUROCARE study which demonstrated poorer survival in the UK than in other European countries for most types of cancer (Chinai et al., 2013).

However, there remains a significant diversity in the purpose, structure, processes and content of MDT meetings, and the degree to which they have been absorbed into clinical practice (Chinai et al., 2013; Maharaj et al., 2021; Raine et al., 2014). Issues commonly observed include deferring discussions due to incomplete medical history, re-discussing the same cases due to inadequate recording of previous discussions, and failure to systematically manage cases to meet local and national targets, such as the RTT deadlines.

Raine et al. (2014) undertook a mixed-methods prospective observational study of 12 MDTs in the London and North Thames area to identify the key characteristics MDT meetings that are associated with “decision implementation”, a measure of effectiveness, and made recommendations in three key areas, which expert stakeholders from a range of chronic disease specialties agreed were both desirable and feasible. These related to the purpose of the meetings (e.g. that agreeing treatment plans should take precedence over other objectives); meeting processes (e.g. that MDT decision implementation should be audited annually); content of the discussion (e.g. that information on comorbidities and past medical history should be routinely available); and the role of the patient (e.g. concerning the most appropriate time to discuss treatment options). Given the core function of MDTs, Raine called for further research experimentally evaluating their effectiveness in a pragmatic controlled trial, with focus on examining the association between MDT decision implementation and improvements in patient outcomes.

Research shows ICT is improving clinical processes by supporting data-driven care and allows patient outcomes to be measured and compared to benchmark performance metrics. The use of health information systems and technology are key enabling factors for building the capacity of MDTs to engage in improvement and implementation projects but there is scant research on how MDTs make use of technology and information systems or the kinds of systems needed (Janssen et al., 2018). Janssen et al. (2018) found that technology was most frequently used to display patient imaging, followed by videoconferencing. To our knowledge, there is no prospective research the impact of a decision-support system on MDT effectiveness and patient care outcomes.

Patient communication breakdowns account for 13.2% of complaints in primary and 16.6% in secondary care (NHSE, 2023). A recent ground-breaking nation-wide research conducted by the Demos & Patient’s Association (2023) reported that 17% patients believe their referrals have been lost and 26% chase up referrals for timely attention (Patient Association, 2023). Globally, clinical communication breakdowns are a leading cause of medical errors (NIH, 2008), implicated as the root cause of >70% of sentinel events (Joint Commission, 2005).

Munro et al. (Munro et al., 2015) examined the impact of multidisciplinary team (MDT) processes on colorectal cancer outcomes. They found that MDT recommendations were implemented in 70.1% of patients (MDT+), with a 5-year survival rate of 63.1%, compared to 48.2% in the 29.9% of patients who were not discussed or without

implemented recommendations (MDT-) ($p < 0.0001$). The adjusted hazard rate for death was 0.73 ($p = 0.047$) for MDT+ patients, indicating a survival benefit, especially in those with advanced disease (adjusted HR 0.65, $p = 0.031$).

4. User Involvement

The Salutare One Referral software was designed and developed by a cross-functional team with expertise in systems' architecture, design, programming, with input from clinicians experienced in MDT meeting operations. The software was tested systematically throughout the development phases to provide assurance of compliance with design specification, performance criteria and industry standards. The following describes the levels of testing which have been completed.

5. One Referral safety and performance testing

5.1. Functional, integration, and performance testing

Functional, integration, and performance testing will be completed by Salutare clinical and engineering staff and clinical reviewers. Functional testing is performed to validate all functionalities of the software in line with the agreed design specification. Integration testing is performed to validate interaction across the system modules to verify that they work well when compiled. Performance testing is completed to ensure the system meets the expected standards in relation to speed and stability prior to deployment for UAT, beta testing, and study feasibility testing. These steps are performed to ensure the production environment that will run the software behaves accordingly and will be completed when the environment is live.

5.2. User Acceptance Testing (UAT)

User Acceptance Testing (UAT) is a type of testing performed by the end user or the client to verify and approve the software system before moving the software application to the production environment. A comprehensive UAT, encompassing all aspects and features of the system as detailed in the UAT Test Plan, will be completed 8 weeks before deployment by Salutare internal reviewers – specifically the software technical managers, head of product, head of operations, and clinical reviewers. This UAT is conducted in the Salutare Azure demo environment, which mirrors the production environment but uses test patient data.

Following a successful internal UAT, the software undergoes an additional UAT review with end users 6 weeks before the anticipated deployment. The UAT testing scenarios include tasks such as sending a referral, tracking its changes, receiving a referral as an MDT after set-up, and finalising the referral from both sides.

During UAT, data on the usability and performance of the software is collected and documented for test evaluation. The criteria for passing UAT are based on the following evaluation matrix:

Criteria	Sub-Criteria	Evaluation Metric
Functionality	All test scenarios must pass without critical errors	0 critical errors encountered All test cases passed
Usability	User friendly interface	User feedback on ease of use

	Intuitive navigation Clear error messages	Time taken to complete key tasks Clarity and helpfulness of error messages
Performance	System response time System stability	Average response time under typical load Number of crashes or performance issues
Security	Data protection Access controls enforced	Encryption standards compliance Audit of access control mechanisms Number of security incidents

Any defects identified during testing are logged with detailed descriptions and steps to reproduce. These defects are then reviewed and confirmed by a product owner before being prioritised and resolved by the development team. Retesting is conducted to verify the fixes.

All UAT findings are risk-assessed for their impact on system safety, performance, functionality and cybersecurity. Issues with potential adverse impacts are addressed and rectified before deployment for beta testing.

UAT is considered complete when all high-priority defects are resolved and the system meets the acceptance criteria. This process requires sign-off from the software technical managers, head of product, head of operations, and clinical reviewers.

Testing documentation is jointly managed by the Salutare head of operations and the head of product. All UAT protocol documentation and result recordings are stored on Confluence, a specialised documentation software for software development.

5.3.Beta Testing

Beta Testing is an external UAT acceptance testing completed by the intended end-users to validate the product's functionality, usability, reliability, and compatibility. This phase is crucial as it provides real-world exposure and feedback from a broader user base.

Beta testing by MDT panel members will be conducted following the successful completion of UAT to the same standards previously implemented for internal UAT. The aim is to uncover any issues that may not have been evident during internal testing, ensuring the software performs optimally in diverse environments and use cases.

Beta Testing is deemed complete when the software meets the acceptance criteria, demonstrating it is ready for deployment. Sign-off is required from the software technical managers, head of product, head of operations, and clinical reviewers before moving to the production environment. All beta testing documentation is maintained on Confluence for future reference and compliance.

Dr Dara Vakili, Study Investigator and Salutare Product Manager, will meet with the MDT chair and Principal Investigator and MDT Coordinator (if applicable) to identify 3-5 MDT panel members to complete the site beta testing. They will all individually run the beta testing protocol and answer a form based on criteria as specified in section 5.2. The form will be hosted on NHS SharePoint so that all stakeholders can access it to assess the software.

This also means that all corrections will be captured and amalgamated into a single form the product manager can hand over to software engineers for fixes.

6. Study rationale

This study aims to assess the feasibility and potential benefits of leveraging the Salutare One Referral software to facilitate, standardize, and partially automate the referral and review of patient cases within the MDT framework. The software offers a promising solution by providing a platform for recording pre-assessment information, thereby replacing manual forms and streamlining data entry. Additionally, it has the potential to integrate with the Summary Care Record, partially populating the pre-assessment dataset and further enhancing efficiency while reducing time spent on list management and administrative tasks.

The One Referral software will streamline the process of requesting and recording inputs from MDT team members, saving significant administrative time and improving collaboration. Furthermore, it can be configured to calculate pre-operative risk scores by integrating commonly used risk algorithms to aid in informed decision-making during MDT discussions, contributing to patient safety and optimizing treatment plans.

The study will be conducted at the Royal National Orthopaedic Hospital Trust (RNOH) Orthopaedic MDT and the Royal Free London NHS Foundation Trust (RFL) Breast Cancer MDT. The choice of these two sites allows for an evaluation of the Salutare One Referral software in two different contexts:

- Complex case review (RNOH Anaesthetics MDT, Royal Free Colorectal Cancer MDT): This setting will test One Referral's ability to handle and present detailed, multifaceted patient information effectively.
- High caseload review (RFL Breast Cancer MDT): The RFL Breast Cancer MDT manages a high volume of cases as part of a standardized cancer pathway. This setting will evaluate One Referral's efficiency in streamlining discussions for a larger number of patients per meeting. (Note: The Royal Free Breast Cancer MDT testing is currently on hold, subject further discussions).

By including both complex and high-volume case reviews, we aim to assess the versatility and adaptability of the Salutare One Referral software across different MDT structures, workflows, and patient populations. This approach will provide valuable insights into the software's potential benefits and challenges in varied clinical contexts, enhancing the generalizability of our findings. The study might be amended following the first phases of tested and expanded to MDTs in other clinical pathways and therapy areas.

RNOH Orthopaedic MDT

The RNOH Orthopaedic MDT meets every two weeks, with approximately 10-11 participants, including Anaesthetists, General Physicians, Medical Consultants, Rehabilitation Specialists, Cardiologists, and as needed, Orthopaedic Surgeons, Pharmacists, Haematologists and Radiologists. The MDT is chaired by Dr Rachel Baumber, Consultant Anaesthetist, the study Principal Investigator. The MDT focuses on discussing complex surgery cases referred by Consultant Anaesthetists, primarily for cancer (e.g. sarcoma) and cardiovascular disease. Each case undergoes team discussion facilitated by a pre-assessment document.

At present, the MDT operates without specialised software, relying on completed documents uploaded to a Shared Drive. Typically, Consultants submitting referrals will circulate a Power Point slide deck, explaining the case being reviewed. A standard form is also completed and submitted. Administrative responsibilities are shared between a

Registrar and the MDT Chair due to the absence of an MDT administrator. A notable time-consuming task involves soliciting comments from various specialists, such as Cardiologists, to ensure thorough evaluation of the patient. The MDT typically addresses a maximum of 10 complex cases per session. Approximately 20% of cases necessitate re-presentation due to missing critical information, such as comorbidities and medication, resulting in delays in patient pre-operative pathways.

Royal Free Colorectal Cancer MDT

The Royal Free Colorectal Cancer MDT convenes weekly, reviewing approximately 30 cases. The team comprises MDT Coordinators, Colorectal Surgeons, Oncologists, Radiologists, Pathologists and Clinical Nurse Specialists. The MDT focuses on discussing complex colorectal cancer cases and findings from surgical procedures, with approximately 50% of cases presented post-surgery. Each case discussion averages 10 minutes, with surgeons typically attending in person. Case submissions are managed through a combined effort between MDT Coordinators and Surgeons.

At present, the MDT operates using paper-based documentation. Cases are recorded on standardized forms, with referrals managed jointly by Consultants and the MDT Coordinator. Cases require comprehensive documentation of imaging, pathology, and clinical findings to enable effective team discussion and treatment planning.

Royal Free Breast Cancer MDT

The Royal Free Breast Cancer MDT meets once per week discussing approximately 90 breast cancer cases, of which there are 60 new cases and 30 roll over cases (cases brought back due to insufficient information). The team comprises MDT Coordinators, Breast Surgeons, Oncologists, Radiologists, Pathologists and Senior Nurse Specialists. The MDT focuses on discussing all breast cancer cases in the breast cancer treatment pathway. Each case undergoes team discussion of cases referred following triple assessment or other pathways. The MDT involvement in this study will be led by the Breast Service Clinical Lead, Dr Muneer Ahmed, Consultant Breast Surgical Oncologist and Reconstructive Surgeon.

At present, the MDT operates without specialised software. Typically, Consultants submit referrals to the MDT Coordinator who lists the cases, and the history is presented verbally with minimal information (name, site of lesion, and essential facts) listed in a single short paragraph. The list typically contains the information for 10 patients on a single side of A4 and is printed and discussed freehand. Approximately 30% of new cases need re-presentation due to missing critical information, resulting in delays in patient pre-operative pathways.

7. Objectives

7.2 Primary objective

The primary objective is to evaluate safety, acceptability and implementation feasibility of the Salutare One Referral Software.

7.3 Secondary objectives

Determination of the following metrics with and without the use of the Salutare One Referral software:

(1) MDT administration time
(2) Completeness of pre-assessment information
(3) Clinical engagement
(4) Time spent by MDT panel members attending meetings
(5) MDT performance rating
(6) Duration of MDT per-patient discussion time
(7) Overall time for MDT meetings
(8) Time from referral submission to the generation of MDT definitive decisions.
(9) Time from referral submission to the implementation of MDT recommendations (OPTIONAL)
(10) Number and rate of cases re-presented for MDT review – breast cancer only
(11) Drug changes to accommodate surgery or any disease optimisation advice
(12) Presence or absence of peri-operative and post-operative complications (OPTIONAL)

8. Study Design

The study is designed as a mixed-methods prospective Before and After Study.

8.1 Primary Endpoint

The determination of the Salutare One Referral Software safety, implementation feasibility and user acceptability in facilitating effective MDT meetings. One Referral software System Usability Score (SUS) and user questionnaires will be administered to MDT panel members. The intent is to utilise the current study's primary endpoint to inform a future protocol amendment and study expansion to further sites to test for clinically relevant and patient relevant outcomes.

8.2 Secondary endpoints

Determination of the following metrics with and without the use of the Salutare One Referral software:

Measure	Assessed via
(1) MDT administration time	Participant questionnaire MDT meetings observation dataset
(2) Completeness of pre-assessment information • Medical history • Risk score completion • TNM recording (radiological and pathological) – breast cancer only	Participant questionnaire MDT meetings observation dataset *Note: If access to the patient's medical record is required, for example if any aspects of the pre-assessment information are missing in the forms, the data would be provided by a member of the direct care team.*
(3) Clinical engagement	Participant questionnaire MDT meetings observation dataset
(4) Time spent by MDT panel members attending meetings	Participant questionnaire MDT meetings observation dataset
(5) MDT performance rating	Participant questionnaire

(6) Duration of MDT per-patient discussion time	Participant questionnaire MDT meetings observation dataset
(7) Overall time for MDT meetings	Participant questionnaire MDT meetings observation dataset
(8) Time from referral to the generation of MDT recommendation	MDT meetings observation dataset *Note: If access to the patient's medical record is require, for example if the MDT recommendation date is not clear in the forms, the data would be provided by a member of the direct care team.*
(9) Time from referral to the implementation of MDT recommendations (OPTIONAL) • "Decision to Treat" (cancer MDT) • Date of operation (Anaesthetics)	MDT meetings observation dataset Participant questionnaire *Note: If access to the patient's medical record is required, for example if any aspects of the pre-assessment information are missing in the forms, the data would be provided by a member of the direct care team.*
(10) Number and rate of cases re-presented for MDT review – breast cancer only	MDT meetings observation dataset MDT meetings recordings MDT referral form (local form or Salutare One Referral form – PDF extract)
(11) Drug changes to accommodate surgery or any disease optimisation advice.	MDT meetings observation dataset
(12) Presence or absence of peri-operative and immediate post-operative complications	Medical records to be reviewed by a member of the NHS direct care team

8.3 The Study Evaluation Model

A Logic Model is used as a theory-based approach to explicitly articulate the underlying theory of change which shapes the desired outcomes and impacts achieved by the Salutare One Referral software as per the study hypothesis (Kaplan and Garrett, 2005; Hayes et al., 2011; Helitzer et al., 2010, Friedman & Wyatt 2006).

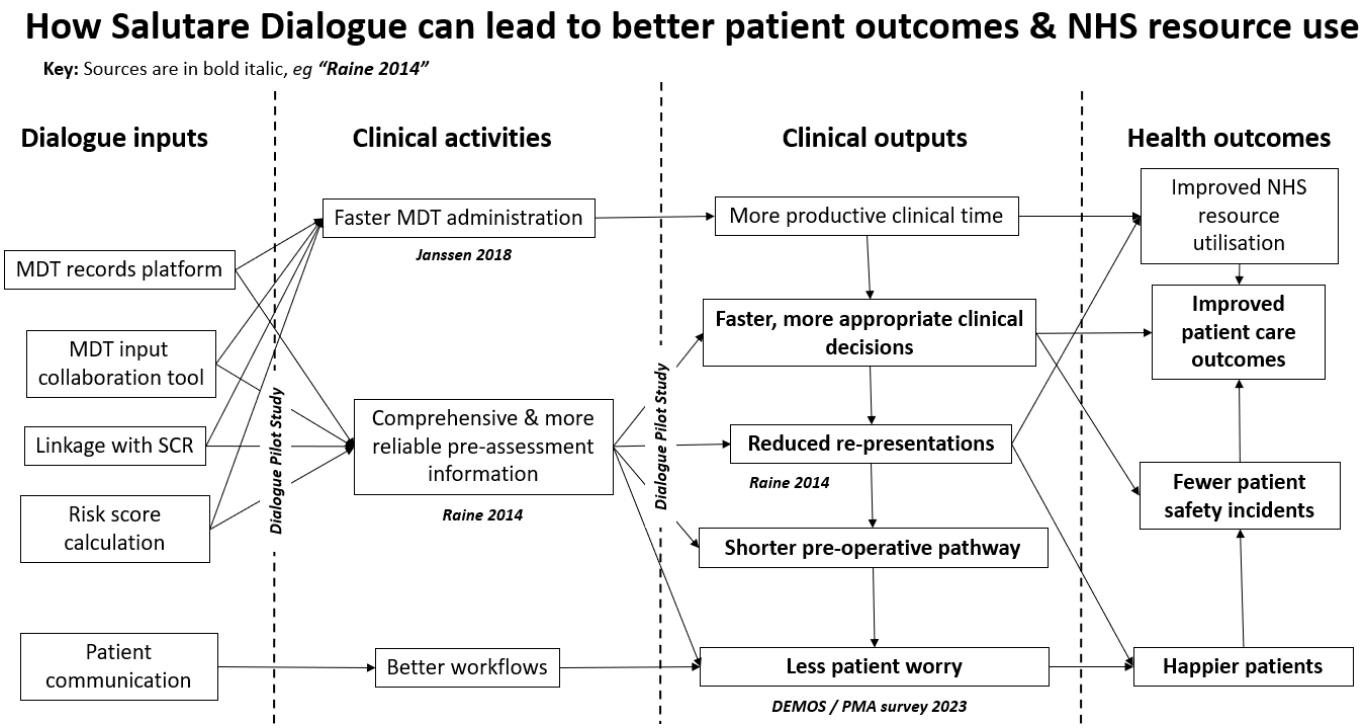

Figure 1: One Referral Logic Model

The chosen secondary endpoints are the observed clinical outputs. The study is a pilot project and therefore not powered to collect data on health outcomes mediated by the clinical outputs. Note: The patient communication module is currently not yet available and therefore will not be assessed in the present study. Observing the duration of MDT per-patient discussion time with and without One Referral contributes to understanding the software's influence on MDT efficiency. This endpoint sheds light on whether One Referral facilitates more concise and productive discussions among team members.

User questionnaires assessing MDT discussions' effectiveness and referral information completeness with and without One Referral provide further qualitative data on the software's impact. Lastly, evaluating MDT preparation time through user questionnaires offers insights into the software's efficiency in streamlining preparatory tasks.

The System Usability Score (SUS) (Brooke, 1996), the only validated tool used in this study, offers valuable insights into the acceptability of the One Referral software. SUS is a simple, widely used 10-statement survey that asks users to rate their level of agreement or disagreement to the 10 statements (half worded positively, half worded negatively) about the software under review.

Usability research within the human-computer interaction field shows that user scores differ substantially over time, with users reporting more favourable scores as they expand their experience with the product (Mendoza and Novick, 2005; McLellan, 2012). Repeated observations of a group of users over time are recommended in order to follow up changes with respect to one or more evaluation variables., with initial use evaluation affording insights on 'discoverability' or 'learnability' and further evaluations elucidating true usability experiences.

8.4 Risk Scores

Breast Risk Scores

PREDICT (Wishart GC et al, 2010) is a risk score that shows how different treatments for early invasive breast cancer might improve survival rates after surgery. It is widely used in breast cancer MDTs and by the Royal Free Breast Cancer team. It is an important clinical decision-making factor for the MDT outcomes and its completion rate in referrals before and after the implementation of One Referral software will be assessed.

Anaesthetic risk scores

The ASA (American Society of Anesthesiologists) Physical Status Classification System (ASA. 2024) is a tool used to assess peri-operative risks for surgical patients. This system categorises patients into six classes based on their preoperative health status, ranging from ASA I (healthy) to ASA VI (brain-dead organ donor).

The SORT is a tool designed to predict the risk of death within 30 days after inpatient surgery. Developed through a collaboration between NCEPOD researchers (Protopapa and Smith, 2014) and clinicians at the UCL/UCLH Surgical Outcomes Research Centre, the SORT model has undergone various evaluations in different patient groups and contexts since its initial release. It is recommended to use this model, incorporating clinical estimates from senior decision-makers and, ideally, the input of a multidisciplinary team.

In this study, the ASA Physical Status Classification System and SORT scores will be employed to evaluate patients' peri-operative risk profiles. The presence or absence of the scores in the pre-assessment documentation will be evaluated as one of the key indicators of the pre-assessment information completeness.

8.5 Statistical Analysis

This study will employ a descriptive approach to analyse the collected data. Prior to finalising the statistical approach, the distribution of key variables will be assessed. In cases where variables show significant skewness, data transformation techniques, such as logarithmic transformation, will be considered to improve normality.

Patient records discussed by the MDT panels will be reviewed and analysed. For the complex case MDTs (RNOH Anaesthetics MDT and Royal Free Colorectal Cancer MDT), all cases discussed during the study pre-intervention, intervention and post-intervention phases will be included in the study analysis.

For the high-volume MDTs (Royal Free Breast Cancer MD), approximately 25% cases are expected to be submitted using Salutare One Referral during the intervention period. A formal comparison of the pre-intervention and intervention study cohort will be made. At the end of the study, raw data will be processed for summary and descriptive statistics. The distribution of times from referral to MDT decision & implementation will be assessed to check if mean or median most appropriate to use.

Normally distributed data will be reported as means with 95% confidence intervals (CIs), while non-normally distributed data will be presented as medians with interquartile ranges (IQRs). Categorical variables will be summarized using proportions or percentages, accompanied by their corresponding 95% CIs.

Pending normality testing using the Kolmogorov-Smirnov Test, a combination of Multivariate Mixed-Effects Models and Generalized Linear Mixed Models (GLMMs), the latter for categorical, ordinal, and binary measures, will be carried out for comparing the system usability scales the acceptance of the null hypothesis.

8.6 Expected Outcomes

The implementation of the Salutare One Referral Software is anticipated to enhance operational efficiencies by improving the quality of pre-assessment information and reducing the time spent preparing for meetings. These enhancements are expected to result in a higher percentage of patients receiving definitive MDT decisions, thereby shortening the patient pathway, including the pre-operative phase for surgical cases. Primary outcomes of the study will evaluate the increased confidence and satisfaction among MDT members in making complex clinical decisions. While this pilot study is not powered to comprehensively evaluate secondary outcomes, future study extension will be conducted to systematically assess the software's effectiveness in supporting MDT meetings and its impact on both patient outcomes and the experiences of MDT members.

8.7 Study Group

The MDT panel members will be invited by the MDT Panel Chairs (Principal Investigators) and Coordinators to invite them to participate in the study. The panel members will be informed of the purpose of the study and time commitment needed to complete the study questionnaires.

8.8 Inclusion criteria

MDT meeting panel members, Coordinators and staff submitting MDT referrals will take part.

8.9 Exclusion criteria

There are no formal exclusion criteria.

9. Approaching participants to join the study

MDT panel members will be invited to participate in the study through their respective Principal Investigators, who act as the MDT chairs. A notification will be sent outlining the study's purpose and the One Referral intervention. While the effectiveness of this study relies on strong participation across the entire MDT, we acknowledge the importance of individual choice and informed consent. Therefore, each MDT member will be asked to provide individual informed consent to participate in the study. This approach ensures that ethical standards are maintained while also recognizing the collaborative nature of MDT work.

MDT members will be provided with a Participant Information Sheet detailing the study's objectives, procedures, potential risks and benefits, and their rights as research participants. They will also receive a Consent Form to document their informed agreement to participate.

Patient consent for the use of their data in the One Referral system, both for the purpose of the clinical treatment and for the research study will not sought.

Clinical treatment: Personal data processing falls under the common law duty of confidentiality. When patients consent to investigation and treatment, this implies consent for care providers to process relevant information to facilitate their referral. Research study: No patient identifiable data will be accessed by external researchers.

Internal NHS staff will observe MDT meetings to collect data on the MDT review duration, quality and outcomes. This data will be pseudonymized by NHS researchers.

10. Study Phases

The duration of each study phase is designed to align with the frequency of Multi-Disciplinary Team (MDT) meetings. This design ensures that an adequate number of MDT meetings are observed in each phase of the study. It is important to note that this study duration is indicative and may be subject to adjustment based on operational factors. For instance, if an MDT meeting is cancelled or rescheduled, the study period might be extended to ensure the target number of MDT meetings is observed in each phase. This flexibility in the study design allows for adaptation to the real-world clinical environment while maintaining the integrity of the research protocol.

10.1. Pre-intervention phase

Prospective review of complex cases discussed by the MDT will be completed.

10.2. Onboarding phase

MDT panel members will be registered on Salutare One Referral via their secure NHS accounts and provided with system training. The system training will consist of an instructional video demonstrating how to:

- Set up accounts via NHS account authentication
- Manage notification settings and configure profiles
- Set up a multi-disciplinary team
- Complete a referral form
- Send a referral form
- Report software issues and request assistance
- What to do in the event of system unavailability

All study participants will be required to complete the onboarding training.

Additionally, the Salutare support team provides assistance for any difficulties via email and an email chat feature. The support team is available during working hours from 8 am to 7 pm, with a response within the same working day. If issues cannot be resolved through the video and email support, a call will be scheduled to address the problem. The Salutare support team will also update instructional materials based on these interactions.

10.3. Intervention phase

The study intervention involves NHS staff interacting with the Salutare One Referral software. The interaction with the One Referral digital tool is classed as and evaluated as a ‘digital health intervention’. The term, ‘digital health intervention’ - first used in the field of digital therapeutics to describe diagnosis, treatment and monitoring of health conditions using software and digital applications (FDA, 2022) - has more recently been expanded to cover the use of information and communication technology (ICT) in support of health and health-related fields, encompassing emerging areas such as the use of advanced computing sciences in big data, genomics, and artificial intelligence (WHO, 2019).

Clinicians participating in the study will engage with the Salutare One Referral software by initiating patient referrals to the MDT through a structured workflow facilitated by the platform. Upon logging into Salutare One Referral using their secure NHS accounts, they are guided through the process of creating referrals, leveraging instructional videos and software-provided completion instructions.

The platform automatically populates essential patient data from the NHS Spine, including demographics. Doctors supplement this data by inputting specific clinical information pertinent to the referral, such as details about the reason for referral, recent test results, and any additional context that could aid in MDT decision-making.

Once a referral is submitted, MDT panel members utilise the platform to engage in virtual discussions with their colleagues as part of pre-MDT preparation. This collaborative environment allows them to share and review essential patient information, including medical histories, laboratory results, and radiology examinations, all seamlessly integrated into the platform. Salutare One Referral ensures that MDT panel members have comprehensive access to the necessary clinical data required for informed decision-making.

During MDT meetings facilitated by One Referral panel members actively contribute to discussions on patient cases, aided by the platform's capabilities to standardise and automate aspects of the referral and review process. As part of this process, doctors complete the risk scores of the respective MDTs including, for example, the ASA and SORT scores for each patient.

Following review completion, panel members export the finalised referrals as PDF documents compatible with Electronic Patient Record (EPR) systems, ensuring seamless integration of reviewed information back into clinical workflows. This integration supports continuity of patient care across healthcare settings and enhances overall efficiency in patient management.

10.4. Post intervention phase

Prospective review of complex cases discussed by the MDT will be completed.

11. Study Assessments

11.1 Baseline Assessment

The Baseline Assessment will be administered to the study participants on the first day of joining the study (Day 0). The Baseline Assessment survey will collect the user baseline information, such as their job role and MDT role, digital competency level and their views regarding the current safety, efficiency and effectiveness of the MDT.

11.2 Onboarding Assessment

The Onboarding Assessment will be administered at the end of the Onboarding Study Phase. This will include the System Usability Assessment (SUS) to collect participant feedback following completion of system training.

11.3 Intervention Assessment

An intervention assessment will be administered to collect participant views regarding the current safety, efficiency and effectiveness of the MDT.

11.4 Post-Study Assessment

Post-study assessment will be administered at the end of the post-study control period. The assessment will comprise the assessment of any safety, efficiency and effectiveness gains/losses associated with discontinuing the use of the Salutare One Referral Software.

12. Data collection from One Referral

KPI type	KPI collected
Engagement with One Referral	Number of users set up on One Referral
	Number of comments by users
	Number of referrals processed by MDTs

This study will employ a mixed reporting strategy to accurately represent different types of data collected throughout the study phases:

Time-Series Reporting:

Variables that can be meaningfully measured and reported for each MDT instance will be presented as a time series. This approach allows for the observation of trends over time and the potential identification of immediate and gradual effects of the Salutare One Referral software implementation. Examples include:

- Number of users engaging with the system per MDT
- MDT preparation time
- Duration of MDT per-patient discussion time
- Overall time for MDT meetings

Aggregate Reporting:

Some metrics are more appropriately reported as aggregate figures over the entire intervention period or for each study phase. Examples include:

- Percentage of cases re-presented to the MDT
- Mean or median time from referral submission to MDT decision implementation

Where possible and informative, we will provide both time-series and aggregate data. For instance, while the percentage of re-presented cases will be reported as an aggregate figure, we may also track the absolute number of re-presentations per MDT meeting as a time series to identify any trends. This multi-faceted approach to data reporting significantly strengthens the study design and allows for a more comprehensive evaluation of the Salutare One Referral software's impact. By incorporating time-series data where applicable, we observe learning effects, showing how users' proficiency evolves throughout the intervention period, while also allowing us to detect any fatigue effects or declining engagement over time. Regular data collection helps us assess the Hawthorne effect, determining whether participants' behaviour changes due to being observed and if this effect diminishes. Furthermore, the post-intervention phase data will reveal any carryover effects, indicating whether the software's impact persists after its use is discontinued (Friedman, Wyatt & Ash, 2022).

13. Schedule of interventions and assessments

Complex case MDTs (Stanmore Anaesthetics and Royal Free Colorectal Cancer)

	Day 0	Day 1 - 28	Day 29 - 42	Day 42	Day 43 - 98	Day 98	Day 99 - 126	Day 126
Baseline survey	x							
Pre-intervention period		x						
Onboarding period			x					
Onboarding survey				x				
Intervention period					x			
Intervention survey						x		
Post-intervention period							x	
Post-intervention survey								x

High-volume MDTs (Breast Cancer)

	Day 0	Day 1 - 14	Day 15 - 28	Day 28	Day 29 - 56	Day 56	Day 57-70	Day 70
Baseline survey	x							
Pre-intervention period		x						
Onboarding period			x					
Onboarding survey				x				
Intervention period					x			
Intervention survey						x		
Post-intervention period							x	
Post-intervention survey								x

High-volume MDTs (Breast Cancer)

	Day 0	Day 1 - 14	Day 15 - 28	Day 28	Day 29 - 56	Day 56	Day 57-70	Day 70
Baseline survey	x							

Pre-intervention period		x						
Onboarding period			x					
Onboarding survey				x				
Intervention period					x			
Intervention survey						x		
Post-intervention period							x	
Post-intervention survey								x

14. Study duration

The total duration of the study will depend on the frequency of MDT meetings and the number of cases discussed.

- Stanmore Anaesthetics MDT and Royal Free Colorectal Cancer MDT: The study duration will be approximately 18 weeks (4-week pre-intervention period, 2-week onboarding period, 8-week intervention period, 4-week post-intervention period)
- Royal Free Breast Cancer MDT: The study duration will be approximately 10 weeks (2-week pre-intervention period, 2-week onboarding period, 4-week intervention period, and a 2-week post-intervention period).

Additionally, 4 weeks are allowed to complete the study data collection.

15. Early Discontinuation/Withdrawal of Participants

This protocol ensures adherence to ethical considerations while respecting the operational dynamics of the study involving multidisciplinary teams, in accordance with UK Health Research Authority guidelines. Given that the collective participation of the whole MDT panel is required for the study to proceed, participants cannot withdraw individually without providing a reason. Therefore, a collective decision by the MDT is needed to pause or terminate the study, ensuring that the integrity and continuity of the research are maintained.

Study participants will be encouraged to contact the study team with any issues and questions and if they wish to opt out. All efforts will be made to resolve any issues. In the unlikely situation that issues cannot be resolved, the research team will discuss appropriate measures, such as allowing the panel members to submit referrals using the existing process.

Participants whose employment at the Participating Organisation is terminated during the study will be automatically withdrawn effective from their last day of employment, with no further data collected after employment ends or after the closure of their email account, whichever occurs first.

While every effort has been made to ensure the safety and efficacy of the Salutare One Referral software, it is important to outline potential adverse events that might necessitate early termination of the study. The MDT panel, in consultation with the study team, may discuss early study termination if any of the following events occur:

- Cybersecurity Incidents: Any breach or attempted breach of the system that compromises or potentially compromises patient data or system integrity.
- Severe Usability Problems: Persistent issues that significantly impair the MDT's ability to function effectively, such as consistent system crashes during meetings or inability to access critical patient information.
- Unexpected Patient Safety Issues or Near Misses: Any incidents or near misses that could potentially harm patients due to software malfunction, such as incorrect display of patient data or loss of critical medical information.
- Prolonged System Malfunction or Outage: Extended periods of system unavailability that disrupt MDT operations and patient care pathways.
- Significant Negative Impact on MDT Efficiency: If the software consistently leads to prolonged MDT sessions or increased workload that cannot be attributed to a learning curve.
- Unresolved Critical Bugs: The discovery of critical software bugs that cannot be promptly resolved and pose risks to MDT operations or patient safety.
- Ethical Concerns: Any unforeseen ethical issues that arise during the course of the study.

If any of these events occur, they will be promptly reported to the study's Chief Investigator, Principal Investigator and Sponsor. The severity and impact of the event will be assessed, and a decision regarding study continuation will be made in consultation with the MDT panel, ethics committee, and other relevant stakeholders. The wellbeing of patients and MDT members will always be the paramount consideration in any such decision.

16 Legal and Regulatory Requirements

16.1 NICE and DH requirements for Digital Health Technologies

The One Referral software is classified as a Digital Health Technology (DHT) to be commissioned for use in the health and social care system. The design of this study follows standards for evaluating the effectiveness of Digital Health Technologies (DHTs) as outlined in the Evidence Standards Framework for Digital Health Technologies (NICE, 2019) developed in collaboration with NHS England, NHS Digital and other stakeholders. The framework classifies DHTs by function and stratifies them into evidence tiers based on the potential risk to users.

One Referral is functionally classed as a ‘system service’ aimed to improve system efficiency and unlikely to have direct and measurable individual patient outcomes. Consequently, it has been classified as Tier A: DHT with potential system benefits but no direct user benefits. This pilot has been designed to generate best practice evidence standard required by the NICE framework to generate evidence of safety, efficacy, and a value proposition to users. As part of this study, we will investigate and evaluate the system’s effectiveness on the duration of the patient pathway, from referral to MDT discussion to the decision outcome implementation, e.g. surgery.

Minimum evidence standard:

- DHT performs its intended function to the scale needed

- DHT meets Government accessibility requirements

Best practice evidence standard:

- Published evidence that DHT has a plausible mode of action that is viewed as useful and relevant by professional experts or expert groups in the relevant field
- Relevant clinical or social care professionals working in the UK health and social care system have either been involved in designing, developing or testing the DHT
- Published evidence to show that representatives from intended user groups were involved in the design, development or testing of the DHT and to show that users are satisfied with the DHT

Salutare Limited abides by the principles of good practice outlined in 'A guide to good practice for digital and data-driven health technologies (DH, 2019 as updated).

16.2 Clinical safety

Salutare, the manufacturer of One Referral, is committed to meeting the highest standards of patient safety in respect of the use of the One Referral software. The Chief Investigator, Prof Kevin Moore, has the lead accountability for scientific conduct of the study. Dr Ameet Bakhai acts as the Clinical Safety Officer (CSO) for Salutare Limited having completed the required Clinical Risk Management Training (e-learning and CSO course) provided by NHS Digital. Dr Bakhai provides clinical safety expertise and oversight, leads the development of Salutare clinical safety processes and documentation, signs off documentation, and oversees compliance with the required standards.

Salutare Limited has developed a 'Clinical Safety Management System', defining a systematic process for the identification of risk and mitigating actions, in compliance with the requirements set out by the clinical risk management standards referred to as DCB0129 and DCB0160. These standards, applicable to Health IT Systems for use within the health and care environment, are mandated under section 250 of the Health and Social Care Act 2012.

Potential risks have been identified and analysed via a review of potential hazards. A Clinical Hazard Workshop has been completed and Clinical Safety Case Report produced. The Clinical Safety Case Report authorises the One Referral deployment in this research study.

16.3 Study risk management

The following mitigations have been implemented to minimise and manage the risks arising from the deployment of the Salutare One Referral software:

- Collaborative Creation and Beta Testing of MDT Referral Form: The MDT referral form will be created in collaboration with MDT panel members and comprehensively beta tested prior to live use. This ensures that the form meets the specific needs and expectations of the panel, and any issues can be identified and resolved early.
- User-Friendly Design: The One Referral software deploys an intuitive, user-friendly design that allows users to complete referrals with minimal training. This reduces the likelihood of errors and enhances the overall user experience.

- Instructional Video for Trial Participants: MDT panel members participating in the trial will be required to watch an instructional video. This video will explain how to complete and send a referral form, request input from others within and outside the MDT, report software issues, and what to do in the event of system unavailability. This ensures that all users are well-informed and prepared to use the software effectively.
- Back-Up System for Offline Operation: A back-up system will be implemented to create an offline copy of a list of patients who need to be discussed at an upcoming MDT. This allows the MDT to proceed even if the system is down due to a disruption in network or cloud services, ensuring continuity of operations.
- Comprehensive Application Support: Application support will be provided to address any difficulties via email and an email chat feature during working hours from 8 am to 7 pm, with responses within the same working day. If issues cannot be resolved through the video and email support, a call will be scheduled to address the problem. This ensures that users have access to timely assistance and can quickly resolve any issues they encounter.
- Regular Software Updates and Maintenance: Regular software updates and maintenance will be scheduled to ensure the system remains secure, up-to-date, and functional. These updates will address any identified vulnerabilities, improve performance, and introduce new features or improvements based on user feedback.

16.4 Adverse Event monitoring

Serious adverse events are any unfavourable and unintended signs, symptoms or a disease associated with clinical study intervention. Adverse events in IMP clinical trials are typically categorised as follows:

- Adverse Event: (AE) Any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment.
- Adverse Reaction (AR) Any untoward and unintended response to an investigational medicinal product related to any dose administered.
- Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR): Any adverse event or adverse reaction that: 1. Results in death 2. Is life –threatening 3. Requires inpatient hospitalisation or prolongation of existing hospitalisation 4. Results in persistent or significant disability/incapacity 5. Is a congenital anomaly/birth defect.
- Suspected Unexpected Serious Adverse Reaction (SUSAR): An adverse reaction that is both unexpected (not consistent with the applicable product information) and meets the definition of a Serious Adverse Event/Reaction.

There is limited literature and regulatory consensus on adapting the above adverse event monitoring framework for the purpose of digital intervention studies. Bradstreet (2019) reviewed adverse event monitoring in mHealth studies for psychosis interventions, concluding that monitoring and reporting of adverse events or effects is largely neglected in these studies, with majority of reviewed studies only reporting levels of acceptability, usability and/or engagement that are poor surrogates for the direct and contemporaneous assessment of adverse or unwanted experiences.

Bradstreet reports standards and outputs of the adverse event procedure used in the EMPOWER (Early signs Monitoring to Prevent relapse in psychosis and promote Wellbeing, Engagement and Recovery, ISRCTN: 99559262) feasibility study of the EMPOWER App, an mHealth intervention to enhance detection of Early Warning Signs of

psychosis and prevent relapse. He recommends that future mHealth studies adopt a pro-active within-study process for the reporting and assessment of adverse events to improve the researcher ability to modify interventions as required and to respond adequately to safety issues as and when they arise.

Unlike the EMPOWER App, One Referral is not classed as MHRA regulated medical device. It is an information management and administration system. Nevertheless we have carried out a full risk and hazard assessment that is included withing our DCB0129/DPIA which are affixed to this submission and include full details of our risks and mitigations.

Any incidents or events related to the operations of the One Referral software, which result have resulted or could have resulted (near miss) in patient care errors, omissions or a delay in patient care provision, will be classed as SAEs and Datix reportable incidents.

In line with the standards proposed by Bradstreet (2019) as implemented in the EMPOWER trial, we will encourage participants to report all negative experiences, in particular examples or types of incidents that may occur arising or potentially arising from the One Referral software, their seriousness and intensity. All reported adverse events will be reviewed by the Chief Investigator, Principal Investigator, Clinical Safety Officer, and other delegated research team members for relatedness and severity. Each incident investigation will be accompanied by Corrective and Preventive Actions (CAPA). Unresolved critical incidents might lead to early study discontinuation.

Detailed Trial Operating Procedures (TOPs) for adverse event reporting will be adopted, detailing the study procedures to encourage study participants to report SAEs.

16.5 Incident reporting

An incident reporting process has been implemented. All study participants will be asked to report any suspected or actual issues to the research team for investigation and resolution. The Salutare research team operates an incident reporting system and provides support within working hours, between 9:00 and 17:00 Hrs. An Out-of-hours IT support is provided by the participating NHS Trust IT service desk, as per standard arrangements.

16.6 Confidentiality

All information collected about study participants in relation to this study will be kept strictly confidential. All participants will be assigned a non-identifiable study number and the data collected in the study will be linked to this number. The study participation itself cannot be kept confidential as the study participants might need to engage with the Salutare study research team. Their participation will also be known to other study participants as they will interact daily as part of the MDT panels.

MDT meetings will be observed (either directly or via reviewing MDT meeting transcripts) by NHS researchers to collect data on the MDT review duration, quality and outcomes. This data will be pseudonymized by NHS researchers.

The patient information processed by the One Referral system includes information required to complete an MDT referral. This includes five key sections for each referral, plus any additional information the referrer wishes to provide. It should be noted that images and histology are not accessed through the platform, but the system is a means to allow transfer requests.

1. Brief medical history
2. Details of prior MDT discussions, treatments, or relevant history
3. The question or questions being asked to the MDT
4. Whether the patient is aware of the referral to the MDT
5. An assessment of frailty or fitness of the patient

This data will be processed for the purpose of direct care provision.

16.7 Cybersecurity

The One Referral software is fully compliant with the Data Security and Protection Toolkit (DSPT) standards. We prioritise the security and privacy of our users by implementing robust cybersecurity measures, including:

- Data Encryption: All data in transit and at rest is encrypted using industry-standard protocols to ensure confidentiality.
- Access Controls: Strict access controls are in place, ensuring that only authorised personnel can access sensitive information.
- Regular Audits: We conduct regular security audits and vulnerability assessments to identify and address potential threats.
- Incident Response: A comprehensive incident response plan is established to promptly address and mitigate any security incidents.
- Compliance: Our platform adheres to all relevant regulatory requirements and best practices to ensure the highest level of data protection.

By maintaining these stringent security measures, we ensure the safety and integrity of our users' data.

16.8 Medical Device Regulations

The existing One Referral software does not fall under the definition of software that is considered to be a medical device, as defined by the Medicines and Healthcare Products Regulatory Agency (MHRA). As such, it is excluded from medical device regulations. Therefore, this research study is not considered a clinical investigation aimed to access patient data for the generation of clinical evidence for CE marking and is not required to be registered with the MHRA. Ethics approval is sought through the Health Research Authority (HRA).

16.9 Ethical compliance

The study will only commence once evidence of d Health Research Authority (HRA) approval is in place. This study will adhere to the principles outlined in the NHS Research Governance Framework for Health and Social Care and the principles of good clinical practice. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate. In conducting the study, the sponsor shall comply with all laws and statutes as amended from time to time, applicable to the performance of the study.

17. Quality Assurance Procedures

The Sponsor Quality Assurance Manager will provide the study monitoring plan. Access will also be granted to the authorised representatives of the inspecting regulatory bodies, the Sponsor organisations, and the funding body, to ensure the study maintains protocol and regulatory compliance and adherence to Standard operational procedures and local policies.

17.1 Study Monitoring

The study may be monitored or audited in accordance with the current approved protocol, Good Clinical Practice (GCP), relevant regulations and standard operating procedures. Lead researchers involved in the study will have up to date GCP training.

17.2 Protocol Deviations

A study-related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process or administration of study intervention) or from Good Clinical Practice (GCP) or any applicable regulatory requirements. Any deviations from the protocol will be documented in a protocol deviation form and filed in the study master file.

The reporting procedure for any potential protocol breaches will be for the study team to report to Prof Kevin Moore, Chief Investigator. Any potential breach will be assessed by Prof Moore and Dr Bakhai (CSO) to establish whether a non-compliance/deviation may be a potential serious breach.

18. Payments and incentives

Study participants will receive Amazon Vouchers valued at up to £20 as a token of appreciation for their time.

19. Funding

Salutare Limited and the North Central London Cancer Alliance are providing funding to undertake this study.

20. Indemnity

Salutare Limited, the study sponsor, is providing indemnity to meet the potential legal liability for harm to participants arising from the design and management of the research, arising from the Sponsor's negligent performance. The participating NHS organisation (host institution) is providing indemnity to meet the potential legal liability for harm to participants arising from negligent study conduct.

21. Intellectual Property

All Intellectual Property Rights and Know-How arising from this study, Salutare One Referral (including but not limited to its design and use alone or in combination with other tools, devices, technology products or interventions,

and/or the study protocol and associated documentation, but excluding any clinical procedure and improvements thereto that are clinical procedures of the Study Site), shall vest in the Sponsor of the study, Salutare Limited.

22. Presentation and publication plans

Research outputs and outcomes will be submitted for publication in healthcare journals and may be presented at relevant conferences or used for any subsequent guidance discussions with NHS executive bodies. Participants will not be identifiable from any summary of findings or papers written for publication. A Steering Committee chaired by the Chief Investigator, formed to supervise the conduct of this research study, will authorize publications and presentations relating to the study. Named authors on the main study publication will include the Chief Investigator, the Principal Investigator and other investigators who have contributed to the design, delivery, and analysis of the study.

23. End of Study

The study end date is deemed to be the date of the last data capture. It is expected to be 10 weeks after the last participants joins the study, allowing for additional 2 weeks of assessment data collection. At the end of study, the Sponsor will archive securely all centrally held study related documentation for a minimum of 5 years.

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