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The development and use of a web application to aid clinician involvement and patient agency in clinical trial recruitment

by
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Abstract

Clinical research is crucial to advancing medicine. There are a range of barriers to patient enrolment in clinical trials, primarily trial awareness. Currently, numerous clinical trial searching sites are available, however, many are targeted at clinicians. The aim of this dissertation was to develop a clinical trials searching website for Urology patients at Morriston Hospital, and to evaluate whether it can increase patient agency, as the hypothesis. This research conducted a literature review of research enrolment barriers and methods for increasing enrolment. The development methodology was an approximation of Scrum and Feature Driven Development. Usability testing was conducted by 33 participants from the local area. Virtual interviews were conducted, where participants adopted fictional patient details and followed instructions to use the site, thereafter evaluating their experience through a survey. A range of qualitative and quantitative questions were used, including Brooke's System Usability Scale. Usability data were supported by demonstrations to stakeholders and patient involvement representatives. Four questions assessed success rates for key steps in site usage, with success rates of 31/33 to 32/33. Both the mean and median System Usability Scale scores surpassed the accepted average website score of 68, at 80 and 85 respectively. Scores ranged from 50 to 100, so individual question responses were analysed. Both demonstrations concluded that the site met initial requirements. This research was a success, indicating that the site facilitates agency. Age and technical literacy were shown to have a similar impact on usability as seen in the literature review. The results are limited as they cannot be generalised to patients. Therefore, the hypothesis can be endorsed but not proved. As such, future work includes involvement of patients in the evaluation, expansion to other clinical specialties, and further exploration of literature.

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I am grateful to my research participants, who provided the primary data source for this work.

Declaration and Consent

DECLARATION

I, Austin Hooper, declare that I am the sole author of this Project; that all references cited have been consulted; that I have conducted all work of which this is a record, and that the finished work lies within the prescribed word limits.

This work has not previously been accepted as part of any other degree submission.

FORM OF CONSENT

I, Austin Hooper, hereby consent that my Project, submitted in candidature for the MSc Software Engineering and Artificial Intelligence degree, if successful, may be made available for inter-library loan or photocopying (subject to the law of copyright), and that the title and abstract may be made available to outside organisations.

Table of Contents

List of Figures

List of Tables

1. Research Introduction and Background

Clinical Trials (CTs, also referred to as “trials” hereafter) are crucial to advancing medicine and finding new treatments. Research indicates a shortage in trial enrolment, and that many patients are not aware of trials appropriate for them. Recruitment is the largest cause of trial delays [1]. This research intends to develop a web application to improve patient awareness, knowledge, and enrolment in Urology CTs in Swansea Bay University Health Board (SBUHB). Usability testing with non-patients, and unstructured interviews/demonstrations will provide qualitative and quantitative data. This data will highlight the application’s usefulness to both patients and clinicians.

Low awareness of CTs is a recurring theme responsible for low enrolment, as described in the literature review. Furthermore, many CT searching websites are aimed at clinicians, using technical language. Ultimately, patients who join CTs need help for their condition, but often do not understand the information these sites present to them. Patients should not require strong medical knowledge to find trials.

Shown by Sully et al. [2] and Walters et al. [3], between 50-60% of randomised, UK-funded CTs either fail to meet their recruitment targets, or face significant delays. Pung and Rienhoff [4] highlight this statistic, noting that low recruitment can lead to prolongation of trials, increased costs, and a study which is lacking, facilitating inaccurate conclusions. Furthermore, in 2021, Zahren et al. surveyed 343 staff involved in clinical research, 70% of whom rated finding eligible participants as either moderately or very significant – the most frequently named research barrier [5].

Agency, particularly patient agency, is a crucial focus of this research. Human agency is defined as: [6], [7, p. 347]:

> *“The capacity possessed by people to act of their own volition… all agency arises from and is relative to the options made available by a person’s position in a wider culture, society, economy, and political system”*

In this project’s context, patient agency refers to patients’ ability to make decisions and control their health care [8].

1.1. Background and Hypothesis

This project originated from a SBUHB research concept to develop a web application to aid patient agency through access to CT information. The intent of this concept was to increase Swansea Urology patient enrolment in CTs, particularly cancer trials.

Further to an approach from a SBUHB Urology surgeon, initial needs and expectations were established. The need for increased trial enrolment was emphasised, which was due to a range of barriers to patient enrolment (further explored in the literature review). Initial ideas concerning the web application were discussed, such as enabling staff to add, edit, view, and delete trial records. A patient search functionality was an expectation, which would link patients to trials managed by staff, based on patients' individual conditions.

The focus is to empower patients, encouraging patient-led trial recruitment. As such, user interfaces will be designed to be as accessible and comprehensible as possible. Also discussed was the lack of uniformity in trial data across Wales, resulting in clinicians' lack of awareness of available trials. This resulted in a lack of uniformity in patient screening for eligibility, which was also determined as a feature of the application.

From this background, the following hypothesis has been defined:

> *Can the use of software systems increase agency in patients with Urological conditions in Swansea, who are searching for clinical trials?*

1.2. Research Aim and Objectives

The research aim and its five objectives outline the goals of the project, and are detailed below:

Aim:

To develop a web application to assist clinician data management and aid patients in finding CTs which are supported by their hospital, and to determine whether it can improve patient agency.

Objectives:

1. Review current literature, developing understanding of both barriers to CT participation and proposed solutions
2. Determine requirements of staff and patient users through unstructured interviews with clinicians
3. Design user interfaces and a database to facilitate requirements
4. Develop a web application which implements feature requirements
5. Evaluate the developed system to test the hypothesis, accomplished via**:**
    - Usability testing of the application with non-patients
    - Unstructured interviews with clinicians through continuous feedback

1.3. Outcomes and Deliverables

This research provides two deliverables. Firstly, a web application is developed to facilitate clinician and patient access to trial information. This facilitates the second deliverable - research data. This data determines the feasibility and usefulness of the application, along with testing the hypothesis.

The web application will be split into patient and clinician portals. The clinician portal facilitates management of trial data, while the patient portal allows patients to

search for trials applicable to them. The application consists of both front-end and back-end code, and a database storing trial information.

The data will consist of both quantitative and qualitative data, concerning the current problem and requirements, along with evaluation of the application. This evaluation determines whether such a system can increase clinician involvement, patient agency and trial enrolment, thus testing the hypothesis.

1.4. Scope and Limitations

Given the computing perspective of this research, it does not aim to determine or alleviate clinical issues involved in CT enrolment. In particular, the literature review focuses on only technical and accessibility concerns for CT enrolment. Regarding application development, for example, a system is developed allowing patients to check if they meet eligibility criteria. The underlying clinical issues surrounding eligibility criteria stringency and other medical topics are outside the scope of this project. Furthermore, much of the background research focuses software applications developed for clinicians, rather than patients. This is a limitation due to a dearth of prior research in the field. However, it has also identified an area that would benefit from further research.

Due to potential ethical and access concerns, data collection and evaluation does not involve patients. This is the primary limitation of this work, as evaluation and data collection are primarily through non-patients and clinicians. Therefore, the research tests whether the application can improve agency when searching for trials, but does not test if it could increase enrolment in a realistic scenario. While this provides valuable research data, it does not incorporate patients, thus not being entirely representative of the intended users. Clinician involvement includes Patient and Public Involvement (PPI) forum staff, SBUHB Urologists, and NHS Wales Health Collaborative.

The timeframe for this project is limited, however there is potential to continue this project in further research. This limitation primarily affects data gathering and evaluation.

1.5. Section Conclusion and Document Structure

This section has introduced the proposed research, a hypothesis, an aim, and its respective objectives. Deliverables and scope have been identified, and key definitions provided.

This document highlights the research, development, and evaluation of the proposed web application. A literature review is conducted in the following section, which informs the research and development. Section 3 evaluates, justifies, and describes the research and development methods, along with planning considerations. Software design and development are described in Section 4, along with justifications of the approaches used. Section 5 provides and discusses the research data. An evaluation and conclusion of the project is conducted in Section 6, along with suggestions for future work. Section 7 reflects on the project. This work's body is followed by a reference list, background reading list, and Appendices.

2. Literature Review

This review of related work consists of two distinct areas. The first relates to research conducted around the problem – CT accessibility, awareness, and barriers to enrolment. These related works focus on identifying barriers and their extent, not on addressing them. Secondly, papers which propose or develop solutions to trial enrolment, and more broadly, patient agency, are reviewed. As described in the project scope, this review does not consider clinical barriers, instead focusing on information, accessibility, and technical barriers.

2.1. Barriers to Clinical Trial Enrolment

This subsection investigates barriers to trial enrolment, considering the effects on clinicians and patients.

There are a wide range of barriers to CT enrolment. Many barriers are strictly clinical, and as such are outside the scope of this project. Three primary barriers to CT enrolment were identified. Firstly, patients have little awareness of CTs which are available to them. Often, patients have no way to find relevant trials. Secondly, clinicians are often also unaware of many CTs, thus making them unable to advise their patients of them. Finally, of the CT matching or searching sites, few are aimed at the patient. The target audience of many of these sites is clinical staff involved in patient care and trial recruitment. As such, most of the information and language used on these sites is not accessible to patients, often requiring advanced medical knowledge to understand.

2.1.1. General Barriers

Mills et al. [9] conducted a review of 33 studies on barriers to trial participation. They determined the most common barrier to trial enrolment, excluding clinical reasons, to be patients' poor awareness of trial opportunities. Also discussed was the complexity and stringency of enrolment conditions, along with the terminology used,

which dissuades potentially eligible candidates. The authors proposed that providing more educational information to patients would alleviate these issues. Little consideration was given to the approach of adapting information to be patient-accessible, which would alleviate the necessity to provide patients with additional information/education.

More recently, Wong et al. [10] shared these findings. They determine three major barriers through oncologist interviews. The primary non-clinical barrier was limited access to resources, affecting both staff and patients. Example resources were listed, primarily educational materials including handouts and websites. Their research also found lack of trial awareness to be an issue. However, unlike the previous paper, this barrier was only found to be present in clinical staff, such as oncologists. Though not explicitly stated as a patient barrier, it is to be expected that patients would also be unaware of CTs if the staff who care for them are not aware. The primary barrier to patients was their negative beliefs or attitudes towards medical research. If patient awareness was increased using a platform to present trial information in accessible language, patient attitudes towards CTs could significantly improve. Their paper gathered information on both patient and clinician barriers. However, patient barriers were discerned through interviews with oncologists, not with patients. Therefore, although their findings are in line with other research, interviewing patients as opposed to clinicians could provide more insight.

In 2006, Agrawal et al. [11] found that in long-term oncology patients (with cancer for a mean of 4.8 years), a reported 10% mortality rate in a trial would not prevent many of these patients from enrolling. Despite this, they determined that the majority of these patients do not understand the trials' purpose or have sufficient information about them. In 2008, Atkinson et al. reviewed 14 prominent CT searching sites [12]. Along with the difficulties discussed by Agrawal et al., these authors found that many sites required the patient to have a good knowledge of their diagnosis, in order to understand descriptions which were "dense with complex terminology". This issue remains prevalent today. ClinicalTrials.gov, a major database of clinical studies around the world, was recently evaluated by Stergiopoulos et al. [13] and Gof et al. [14]. Both studies shared findings, in particular that using the website from a patient's perspective would not yield full or accurate results. Gof et al. determined that site-specific contact information was unavailable for more than 40% of entries, hindering patients' agency.

They suggest that an interface upgrade is warranted, to improve patients' opportunities of finding trials.

In 2016, Ridgeway et al. explored the perspectives of patients' family members searching for CTs [15]. They found that patients' family felt unqualified to search for trials, and found it difficult to identify appropriate trials, despite the presence and use of trial searching websites. A 2019 study by Isaksson et al. used questionnaires and discussions with study personnel to identify recruitment barriers [16]. Many identified barriers were resource, medical or management related, therefore beyond the scope of this dissertation. However, study personnel identified patients' fear of side effects, fear of not receiving the best treatment, and difficulty understanding trial randomisation, to be primary patient barriers. Patients' medical knowledge was not discussed, suggesting that this was not a perceived barrier.

Stryker et al. determined that patients who enrol in trials early in their discussion reported themselves as less informed than later enrolees, regarding a particular trial ($p=0.02$) [17]. The highlighted implications for medical practice primarily consist of ensuring CT participants fully understand risks and benefits to participation. An earlier study by Cox provides an alternative viewpoint, finding that patients' agency was often limited as they were not well-informed about trials, and often believed recruitment decisions should be made by their physician [18]. Additionally, verbal communication was found to be more useful by many patients, for example via consultations, or, as Cox suggests as a practice implication, via patient discussion with research/trial nurses. A 2017 study by Anderson et al. evaluated over 12,000 responses to a survey identifying the views of both CT participants and nonparticipants [19], though heavily imbalanced. The survey found that most of the public (90%) believe CTs to be "generally safe". This study appears to be robust, including over 12,000 responses from 68 countries. Despite this, its finding regarding safety perceptions disputes other conclusions highlighted in this literature review, particularly those of Sedrak et al. [20] in Section 2.1.2, and Friend et al. [21] in Section 2.1.3. No reason for this anomaly was identified.

Simon and Hegedus [22] selected 66 CT websites they found through internet searches for "cancer clinical trial", and evaluated their content and quality. They noted that many could be useful to patients and clinical investigators, but that a large

proportion were difficult to navigate and understand, some relying on scientific language. A 2008 Datamonitor Consulting report [23] shared these findings. It evaluated four major CT websites, with mixed results. Some were found to have extensive information, although they were not user-friendly due to interface and language concerns. Others were accessible and readable but provided little detail and no contact information. Monaco and Drills [24] discuss in further detail reading levels of trial websites. 39 National Cancer Institute Comprehensive Cancer Centre (NCI CCC) websites were evaluated, finding that most trial descriptions were written at university reading level. They acknowledged the necessity of some medical language, but suggested trial information be presented more accessibly. One major acknowledged limitation of the study was the lack of inter-rater reliability. Despite this, their findings align with those of aforementioned papers evaluating different sites, such as those of Simon and Hegedus, and Datamonitor Consulting**.**

2.1.2. Older Patients in Clinical Trials

Older patients, particularly those over 65 years old, are underrepresented in CTs, particularly cancer research [25]–[27]. The enrolment barriers for this group are partly shared with the overall population, but partially unique. Low enrolment is unfortunate, especially considering the older population has been shown to participate in medical research for reasons which differ to Adolescents and Young Adults (AYAs) [28].

Technological barriers and trial awareness have been shown to be more prominent in older patients. These two factors could be tightly coupled, as technological barriers can limit access to information. Sedrak et al., prominent authors in the field, used semi-structured interviews to determine medical oncologist's views of trial enrolment in older cancer patients [29]. Patient awareness and understanding were identified as significant barriers. Community oncologists identified these barriers more frequently than academic oncologists – 45% of community oncologists, versus 10% of academic oncologists. Comparable to Wong et al.'s approach, this paper is also limited in that it ascertained patient barriers through discussion with oncologists, not patients. This approach also identified oncologist time as a limitation, given the time investment required to manage and enrol patients (identified by 11% of

oncologists). Both academic and community oncologists shared the view that lack of understanding of CTs impacts older patients more than younger ones, particularly regarding the expectation/concern of being “experimented on”. The authors acknowledged the limitation that those oncologists interviewed were all within a single health network, with a limited sample of 44 oncologists. This finding regarding patients’ expectations of medical research was found to be generalisable to many patients regardless of age, by Unger et al. [30]. They investigated patient attitudes towards research and found that patients frequently reported feeling “uneasy” or “fearful” about the prospect of participating in medical research. It was determined that the research process must be further explained to patients. This could be facilitated through a web resource.

Sedrak et al. also conducted a systematic review of research papers in this area [31]. This work shared findings of their previously discussed paper, along with finding transportation concerns, and perceived participation burden were prevalent, possibly linked to lack of understanding. Furthermore, Sedrak et al. conducted another review of 13 studies [20], highlighting that only 24% of US CT participants are above 70 years of age. This work discussed in further detail older patients’ barriers to trials, citing emotional burden, patients believing they are “too old” for trials, and concerns of trial efficacy and drug toxicity. These factors form part of the overall concern of patient knowledge/awareness. A patient-focused information and recruitment website could alleviate these issues by providing understandable explanations, which are rarely included in generic recruitment sites. The paper provides recommendations to improve older adult inclusion and participation in medical research, though focuses only on clinical issues and patient feedback. The paper makes no suggestion for improved resources for patient access. It also supports the findings of Fearn et al. in 2010 [32]. Their work determined that older patients report altruistic reasons for trial participation, although also found that these patients did not fully understand trial information. It discusses the requirement for readily available, understandable trial information, and the importance of good communication with older patients about trials.

Liu et al. recently investigated strategies to improve older adult participation in trials, particularly recruitment barriers [33]. Their findings echo those of earlier studies, suggesting that they remain relevant to some extent. Their paper suggests further research should be conducted to determine older patients’ desires and needs from

medical research, and to further integrate technology, primarily telehealth, into medical appointments and trial enrolment. They suggest telehealth is used to reduce the burden on patients and healthcare providers, by improving access to care and information. This was suggested despite low adoption of technology among older patients. This paper acknowledges the necessity for additional research into the feasibility, adoption, and sustainability of telehealth for CTs.

2.1.3. Younger Patients in Clinical Trials

The AYA population (commonly 15-39 years of age [21], [34], [35], as per the National Cancer Institute [36] definition) is not well-represented in medical research. Less AYAs are enrolled in clinical trials than the populations of either children or adults [37]–[39]. Few trials fully accommodate the AYA population. For example, in 2019, de Rojas et al. [40] searched ClinicalTrials.gov for 10 malignancies relevant to AYAs. Of 2,764 results, 2,176 were analysed. 79% of these were not tailored to AYAs; only five trials were AYA-specific. The AYA population shares many of the barriers faced by the general and older populations. However, this age difference creates a range of different barriers not present for the older population, while alleviating other barriers. Given the low number of trials tailored towards AYAs, raising awareness of these trials is critical.

In 2021, Ellis et al. explored Australian AYA enrolment barriers by forming a committee of experts [37]. They determined that trial leads/investigators often specialise in adult or paediatric oncology, but rarely both. The identified barriers were primarily clinical and administrative, not patient related. For example, a primary barrier was lack of understanding of ethics and governance requirements needed to establish trials which are open to paediatric and adult patients. They highlight that many trials which may be suitable for younger patients are not made available to them. These points may not be entirely generalisable outside of Australia, but do align with other discussions in this field.

Identifying patient barriers and motivators, Zolkipli-Cunningham et al. conducted an online survey of both adult and AYA groups with Mitochondrial Disease [41]. While not focused on comparing age groups, the authors noted that trial treatment type and

design preferences were not influenced by age. Lee et al. explored the differences between factors affecting trial participation in adult and paediatric patients with Cystic Fibrosis [42]. The young patient cohort was represented by parent responses, which the authors note may not fully represent their child's views. A response bias was acknowledged, respondents were those with fewer enrolment barriers. Correspondingly, 30% of adult and 43% of paediatric patients reported no barriers to participation. This conflicts with the above research, which indicates paediatric patients would be more likely to encounter barriers. Compared to the adult cohort, parents of the paediatric cohort were less comfortable with treatment via injections. Views of young patients may not be represented by their parents.

Siembida et al. [34] and Friend et al. [21] conducted article reviews of 13 and 17 AYA cancer trial enrolment papers, respectively. Siembida et al. found that two of 13 papers addressed awareness as an issue. These studies determined eligible patients were not made aware of some potentially suitable trials by their clinicians. Furthermore, two studies created AYA-specific oncology programs which were found to improve CT participation. This success was attributed to employing dedicated staff to aid in connecting AYAs with available CTs. The web system developed for this dissertation will help patients contact research nurses.

Similarly, Teenage Cancer Trust is at the forefront of cancer care and support for young people in the UK, collaborating with the NHS [43]. They provide specialist support such as youth support and nursing staff, along with specialist wards for AYAs, featuring games consoles, wireless networks, pool tables etc. [44]. The discussions of Siembida et al. mirror the earlier findings of Friend et al.; they determined the primary barriers to AYA enrolment were low AYA-specific trial numbers, and patient knowledge. They highlighted that many trial providers target discussion at parents of younger patients, emphasising that younger patients benefitted from direct communication. Friend et al. suggest that further explanation of the trial's treatment may alleviate patient fears and improve enrolment. It was suggested that trial providers convey that CTs are the "gold standard" of medical research, as argued by Misra [45]. Forcina et al. [46] conducted a review of cancer trial literature assessing perceptions and attitudes of the AYA population. They found that fear-provoking terminology and being overwhelmed with information were significant concerns of AYAs. Many AYAs were dissuaded by the expectation of enrolling at the time of diagnosis.

Westen et al. [47] explored barriers and facilitators to CT participation in AYAs with Type 1 Diabetes. They found many barriers also occur in the older population, such as concerns of drug side effects, and critically, patients receiving limited information about trials. However, this study also determined that the possibility of missing study or work were barriers for the AYA population, a conclusion shared by Anderson et al. [19]. Meanwhile, Westen et al. found that older respondents were more concerned with having access to the drug after the study concluded. They proposed that recruitment should be tailored to different age groups, such as making online recruitment available to younger participants.

2.2. Resolutions to Enrolment Barriers and Facilitators of Patient Agency

This subsection explores approaches to mitigate enrolment barriers, and applications which aid clinician involvement and overall patient agency. This subsection also explores social media as an affordable and effective alternative to traditional CT recruitment.

2.2.1. Trial Recruitment and Generic Agency Applications

Various digital approaches can benefit patient agency. Hanna et al. created and evaluated a Personally Controlled Electronic Health Record (PCEHR) system for an Australian health service [48]. The system was evaluated through semi-structured interviews with 12 patients. This is a limited number, although this allowed more in-depth discussion with each patient. Relevant to this dissertation, the primary perceived advantage of PCEHRs was improved quality of care through improved patient-clinician communication. Another highlighted benefit was that all data was available from one source. Hoogenbosch et al. further explored this area, analysing use of a hospital patient portal [49]. 439 patients completed a questionnaire about the portal. 32% indicated using the portal, 31% were aware of it but did not use it, and 37% were

unaware of it. Chronic illness was associated with increased use of the patient portal. Surveys indicated that overall, portal users found it beneficial.

Marien et al. developed a medication reconciliation system to combat medication discrepancies and increase patient engagement [50], [51]. The system consisted of a patient application for reporting medication usage, and a clinician application to manage medication based on patients' reporting. This application was well-received in its evaluation by 48 clinicians during usability testing – clinicians were its focus. Although deemed useful, the authors noted the necessity to increase interoperability between the two applications. Sardaneh et al. developed an electronic medication management system, also for the purpose of medication reconciliation [52]. The authors highlighted that clinicians recorded medication reconciliation in a more timely manner once using the system.

A 2019 review by Qudaha and Luetsch explored how mobile health applications impacted patient-clinician relationships [53]. Patients reportedly perceived a positive impact on the relationship with their healthcare provider after adopting mobile health applications. Also highlighted was that the use of mobile applications supported patients in becoming more active in managing their health – this is critical to patient agency.

In 2005, Metz et al. evaluated OncoLink, stated to be the oldest and one of the largest cancer information resources on the internet [54]. This site launched in 1994 and added patient trial matching in 2002. In a 15-month timespan, 627 eligible patients were found through the site, demonstrating its effectiveness. Online applications were approximately split equally between patients, and family on their behalf. This finding is relevant, as this dissertation aims to aid not only patients, but their family in finding trials. Importantly, this paper found that even in 2005, patients and family were willing to use the internet to find CTs and enrol on them.

In 2017, Mohs et al. detailed the impact of a newly developed web-based recruitment application [55]. They found that this application benefitted trial recruitment, though only with considerable advertising. This finding is limited, as the authors state more data is required to determine the exact impact. Also noted was that use of site-specific trial databases was considered effective by 94% of documented sites. These findings were shared by Fenner et al. [56], who explored Facebook

advertising for attracting patients to their trial website. They found that the combined cost of the website and advertising was US $20 per eligible patient, deemed highly cost effective. Social media for recruitment is further discussed in Section 2.2.2.

Toddenroth et al. implemented a CT recruitment monitoring dashboard for clinicians and trial investigators [57]. This locally deployed Electronic Data Capture (EDC) application was well-received by trial investigators and deemed extremely useful on the assumption that it can be modified to support automatic, daily updates. A more basic version of this functionality could be implemented for this dissertation, providing a monitoring and feedback element for clinicians. Authors noted their study was limited in that they did not ascertain feedback for individual features, only the overall application. Mattingly et al. developed a similar dashboard to aid researchers in managing trial enrolment [58]. In surveys of researchers and trial managers, 77% felt that the application made management and communication “easier” or “much easier”. However, this finding is limited as the study included only 23 staff.

Cohen et al. developed a trial matching website for breast cancer in 2012 [59]. 12 research sources contributed a total of 55 trials to the developed website. In the first 14 months, the site received 733 registrations from visitors, of which 407 matched to at least one trial. Surveys were sent to patients who completed the site’s health history check. Of the 20% who responded, 31% then contacted the research site. A total of 16% (52% of those who contacted a site) were found to be eligible. This resulted in 6% of patients who responded to the survey enrolling in a trial. This study was limited in that only those who completed the health history check were invited to discuss and disclose their eligibility and enrolment statuses.

Brøgger-Mikkelsen et al. recently conducted a systematic review of research on online trial recruitment [1]. This study reviewed 61 papers, and found online recruitment through advertising or trial websites to be significantly more effective at finding and recruiting patients than traditional methods. Also highlighted was the substantially lower cost per enrolled patient of online compared to traditional methods (US $72 vs US $199, p=0.04).

In 2007, Atkinson et al. developed a prototype CT searching system for breast cancer patients [60]. Two small patient group discussions were held to evaluate patient experiences and the website. The primary conclusion was that patients were positive

and optimistic about using the internet to search for CTs, although sites should meet their expectations for privacy and credibility, and be sensitive to their situation. They recommend developers to conform to usability guidelines and test with the target audience. This paper used two small sample sizes of only 8 and 7 patients.

2.2.2. Social Media in Research Recruitment

Literature in the area of social media for CT recruitment is predominantly focused on Facebook, likely due to its popularity. Therefore, this platform will be the focus of this subsection. In 2020, Sanchez et al. reviewed 176 articles surrounding social media for mental health research [61]. They found that Facebook was employed by 92.6% of these studies. Paid advertisements were the predominant strategy, used by 60.8% of studies. The primary conclusions of this paper relate to efficacy and ethics. Compared to other methods, social media recruitment was found to reach more hesitant and/or vulnerable populations. Social media was found to be economically effective for mental health research recruitment, although at the cost of methodological and privacy concerns. The characteristics of subjects recruited through social media versus traditional recruitment was not addressed.

Ethical concerns were further addressed by Crawford et al. [62]. They also acknowledged that online methods allow contact with more difficult to reach patients. They state there is little ethical and legal guidance on social media recruitment. Citing Moreno et al. [63], they discuss maintaining online privacy, confidentiality, and anonymity; obtaining and sustaining informed consent; and the potential for participant misinterpretation as significant issues. Bragard et al. concur with these findings [64].

Whitaker et al. reviewed 35 studies in 2017, predominantly US-based, and also concluded that social media enables access to difficult to reach demographics [65]. They determined the median cost per participant of only US $14.41. Ramo et al. explored Facebook for recruiting young adult smokers in 2014 over a 7-week period [66]. This cost US $0.34 per click. 10% of interested parties were eligible, of which a further 39% consented. Their average cost per eligible, consenting participant was US $8.80. In 2016, Thornton et al. reviewed 110 articles using Facebook for CT recruitment [67]. Of studies which reported cost per completing participant, the cost

ranged dramatically, potentially due to methodology adopted. There was little variation in cost per research topic. The review also found that of studies examining the representativeness of their patient sample, 86% concluded that their recruited patients from Facebook were similar to those recruited via traditional means.

In 2019, Sedrak et al. [68] interviewed 44 physicians to ascertain their perceptions of social media for recruitment into cancer CTs. The most cited advantage was increased trial awareness and visibility. However, the increased administrative burden and risk of misinformation were acknowledged. Furthermore, the need for restructuring and employing personnel with social media expertise was also cited as a barrier to adoption. This study represents the perceptions of staff from one institution only, so may have limited generalisability.

A 2018 study by Akers and Gordon [69] provides advice for clinicians recruiting through Facebook, based on experience. Facebook was described as especially useful for raising awareness of a study within only the eligible demographic, and for studies targeting specific geographical groups. Furthermore, it was found to be useful for patients who are not actively seeking help for their condition, and for topics which friends or family are likely to refer them. It was recommended that a Facebook “fan page” be created for any study connected to Facebook advertisements. The study home page, linked to by advertising, was emphasised – it was advised to be pleasing to the eye, welcoming, and aimed at a broad audience. It was also advised that a robust participant management system be in place.

A 2021 study by Zlotorzynska et al. evaluated various social media platforms for research recruitment in young men [70]. Facebook advertisements yielded the lowest cost per eligible patient, while Instagram returned the highest proportion of eligible minority patients and under the age of 18. Twitter had the lowest click-through rate (clicks ÷ impressions, where impressions are the number of times an ad is viewed) and higher cost per click than Facebook and Instagram. Parker et al. also recently explored a wide range of social media platforms for recruiting substance-using and minority AYAs [71]. Contributing to the findings of Zlotorzynska et al., they found Facebook provided the largest quantity of eligible patients (42.1%), followed by Grindr (23.2%) and Instagram (10.8%).

In 2013, O'Connor et al. explored Twitter for health research recruitment [72]. They deemed Twitter to be cost-effective, an accessible way to participate in research, and that it enables engaging with difficult to reach populations. Twitter was praised especially for its use in sharing trial information via retweets. A UK study by Bisset et al. utilised Twitter for surgical trial recruitment [73]. The 500-patient recruitment target was surpassed within 11 weeks, finally reaching 952 patients, and having 200,000 impressions. Authors noted the positive impact of branding on tweet engagement.

2.3. Section Conclusion

This section has reviewed two areas of literature. Barriers have been explored, determining awareness, availability, and readability of resources to be problematic. Barriers and facilitators vary between age groups, particularly regarding technological approaches to recruitment, and research perceptions. Software applications have been explored, demonstrating their effectiveness in increasing patient agency and aiding clinicians in caring for patients. Social media and web applications have been shown to be extremely effective and inexpensive in recruiting, especially for hard to reach populations. In future work, this review could be expanded to explore healthcare barriers among further areas of diversity, including ethnicities and minorities. The next section conducts a methodological review of both research and development methods.

3. Methodological Review and Planning Considerations

This section describes and reviews the chosen methodologies and expected results. Both research and development methodologies are discussed and justified. Resource and ethical considerations are discussed in relation to methodological approaches. Additionally, the project timeline is detailed.

3.1. Research Philosophies and Approaches

This research took a mixed methods approach, incorporating both positivistic and phenomenological approaches and strategies. This is due to the project's focus on people and their experiences [74]–[76]. Mixed methods, primarily through usability testing and unstructured interviews, provided qualitative and quantitative benefits [77], [78]. Subjective, qualitative data was used to aid generalisability, while quantitative, precise data was beneficial in increasing reliability, and supporting a primarily deductive approach and hypothesis [75].

3.2. Research Methodology

3.2.1. Literature Review

A literature review was conducted, primarily focusing on patient perceptions and barriers to CT enrolment, and methods adopted to mitigate any barriers. The literature review provided clinical, contextual information to this computing-based approach. However, the literature review focused primarily on technical, awareness, and accessibility barriers and facilitators within patients' journeys of finding and enrolling in medical research. This review explored computing-based approaches to addressing clinical problems, remaining within the remit of this degree programme. The literature review has also informed the research and development methodologies and approaches taken.

3.2.2. Software Development

Software development has entailed design and implementation of a database-driven web application. Given the widespread, highly accessible nature of websites compared to other types of application, the choice of application platform was straightforward. Server-side web development used the PHP server-side language and MySQL database server, due to their low footprint, compatibility, and familiarity with these technologies. This combination is an industry standard, part of the Linux, Apache, MySQL, PHP (LAMP) stack. This development was applied as a vehicle by which research data was generated. However, this software is also the primary deliverable to the industry partner of this project. The software development methodology is detailed in Section 3.3.

3.2.3. Usability Testing

This work's primary data source was usability and User Experience (UX) testing. UX focuses on understanding applications' users, needs, expectations, abilities, and limitations [79], [80]. Usability, part of UX, is the extent to which a product can be used to achieve specific goals [81]. For web applications, this also encompasses web accessibility – the design and implementation of websites such that they are inclusive to all, ensuring there are no barriers to people with disabilities [82]–[84].

Usability testing incorporated traditional user-testing, a widely used method for evaluating patient information websites and leaflets [85]–[87]. In this context, user-testing refers to the process of participants testing an information source or application during an interview, determining whether they can find key information or use key functionality [85]. Putnam et al. [88] described adapting the SUS for user-testing, which provided insight, along with the work of Sheridan et al. [87], who explored user-testing of multimedia information about CTs.

Participants were adults found through a research call in the local area. It was not possible to test the site with patients. Participants were provided with a patient persona and medical details to adopt, which were used when searching for trials, allowing participants to emulate a hypothetical patient. Identical patient details were

provided to each tester. Although this only explores a single patient's scenario, this approach was adopted for result consistency. The patient details provided are summarised in Table 3-1. Trial data was adapted from the ClinicalTrials.gov database and approved by the Urology surgeon stakeholder. This measure ensured the data represented a real and appropriate scenario. Testing was conducted on participants' personal devices due to social distancing limitations. This provided the benefit of participants using familiar devices. Additionally, this provided the benefit of a real-world scenario. However, it is acknowledged that this is not an entirely controlled environment.

Table 3-1: Usability testing patient details

Condition Details	
Condition specialty:	Urology
Affected organ:	Prostate
Specific condition:	Localised prostate cancer
Clinical Background	
Have any other conditions?:	No
Had any treatment for your condition?:	Radiotherapy
Taking any medications?:	No
Any allergies?:	Contrast dyes
General Background	
Age:	43
Biological sex:	Male
City of residence:	Swansea

Each participant evaluated the site through an interview with verbal instructions to use the site, followed by a Microsoft Forms survey. This interview took place via either phone calls, or video calls with screen sharing. Interview medium was logged in the survey to test whether the communication format affected the outcome. Participants were also asked to indicate whether they used a mobile or desktop device when evaluating the web application, as this may have impacted their experience. Furthermore, participants' self-reported technical literacy and optionally disclosed disabilities were collected to ascertain their implications on site usability.

Initially, the research was trialled as a single survey consisting of both written instructions and feedback questions. This was modified into the interview format due to its complexity.

The participants were introduced to the project, verbally briefed on research consent, and required to indicate consent via a full screen overlay on the website. Additionally, consent was ascertained in the online survey. Instructions were developed in Microsoft Word, and verbalised to participants. This approach was adopted to ensure consistency in the instructions provided. These instructions are included in Appendix A, while a PDF version of the online survey is included in Appendix B**.** With few exceptions, participants were not provided advice or guidance to complete the instructions. When asking for advice, participants were advised to use the site as they thought they would if they were using the website alone, without the researcher present. Those who were unable to complete an instruction step were advised, and this was indicated in their survey responses. The following stages of the patient journey were evaluated during the testing:

- Finding the trial search functionality
- Inputting patient medical details into the trial search form
- Navigating between trial search results to view individual trials
- Evaluating key trial information, primarily location and eligibility criteria, against the given patient scenario
- Contacting a trial contact point via a web form, and finding contact information

It is reasonable to assume that the participants did not have the intrinsic motivation that a patient group would. Thus, the data derived is not entirely representative of the expected users of the site. Testing with a patient group would be essential to any further stages of this project.

The System Usability Scale (SUS) [89] was used to generate highly valid and reliable quantitative data about qualitative issues within the sample group [90]. This scale consists of ten questions, with Likert-style answers. SUS questions intentionally elicit either strong agreement, or strong disagreement, alternating each question. There are two overlapping variants of some questions, phrased differently. Brooke stated that these approaches were taken to prevent response biases and ensure participants properly read each statement [89], [91]. These questions were used to calculate a usability score from 0-100, where average usability applications score 68 [91]. Immediately after completing the instructions, participants were asked to respond to the survey, containing the SUS, as recommended by Brooke [89]. The SUS is effective at differentiating those who successfully used an application from those who experienced difficulty [92].

During the survey, data was generated for success rates at each step of using the site, providing quantitative data, and indicating the usability of website usage milestones. Furthermore, the survey ascertained whether each participant could find a trial which their patient persona was eligible for, giving an overall success rate. Finally, participants were asked open-ended questions, providing qualitative data. These questions asked what they liked most about the site, experienced difficulty with, liked about this method of searching for trials, and their opinions on how the site could be improved.

This usability methodology was limited by the ongoing COVID-19 pandemic. Observation during testing was limited due to social distancing, only available with those participants comfortable and able to share their screen during a video meeting. Ideally, eye tracking would be included, though this is more suitable for future work. It is difficult to collect data on which browsers participants may use, as many may not be sure of this. As per Mozilla [93], browser data can be collected through HTTP User-Agent request headers. However, this cannot be communicated to the survey; as such, it was omitted.

3.2.4. Unstructured Interviews and Meetings

Unstructured interviews were conducted throughout development, incorporated into the agile approach. These provided clinician-level feedback and contextual information. On completion, the application was demonstrated to SBUHB Urology clinicians, and later to the NHS Wales Health Collaborative, to evaluate outcomes. These demonstrations encouraged feedback and evaluation from clinician and business perspectives. These views are highly valid as clinicians are heavily involved in the CTs process. These interviews and demonstrations were limited from a research perspective in that they ascertained the viewpoints of a small number of clinicians within the same institution. However, they were appropriate for the development, as the clinicians were stakeholders.

The data aided in testing the hypothesis and understanding views and motivations of clinicians [94], while providing modification suggestions for the application. However, this primarily impacted the development.

3.3. Software Development Methodology

Development took a loosely Agile approach, although this is not fully achievable as an individual developer. The methodology adopted was most comparable to Scrum, particularly from the weekly or fortnightly sprints and meetings. Scrum is a framework focusing on allowing developers to address complex, adaptive problems, while delivering high-value products [95]. Scrum is a traditionally team-based methodology – adapting it for an individual does not retain all of its principles and benefits. Despite this, the process was very effective, as also found by Pagotto et al. [96].

Each meeting was effectively a sprint planning meeting, sprint review, and sprint retrospective combined, due to the small-scale nature of this project. The workflow included a small proportion of Waterfall-like development, where each sprint involved designing, implementing, and testing, as is typical of Scrum sprints [97], [98]. Unlike the true Waterfall methodology, however, this was not linear.

During and between progress review meetings with the customer, a Urological consultant, the development backlog was consulted to determine steps for the next sprint. This approach incorporates highly iterative development with traditional incremental development, although primarily iterative. Frequent iterations facilitate continuous customer/stakeholder feedback and software modifications in a timely fashion to meet continuously updating requirements [99]–[101].

This approach was well-suited due to the regular stakeholder involvement. This project was not developed purely for personal interest or curiosity, but as a live project with real-world implications both within and outside academia.

Development also took inspiration from Feature Driven Development (FDD), although, as with Scrum, not fully. FDD is both iterative and incremental, encouraging regular builds to be made available to the customer, also emphasising collaboration [102], [103]. Each iteration focused on implementing one, occasionally two, new features. Features were planned based on the web pages which would be associated with them, along with any required Create, Read, Update, and Delete (CRUD) operations. Design and development were approached by features and associated web pages, as opposed to user stories, due to the small-scale, confined nature of the features.

3.4. Resources

Few technical resources were required. A basic computer with the appropriate development environment installed was the extent of development resources. An Apache web server, along with PHP and MySQL installations, and a code editor, were required. The application was stored locally in the development environment. The application was not hosted online for usability testing, as the home networking was configured for port forwarding, and this testing was conducted on a small scale. Microsoft Office facilitated data collection, evaluation, and online video meetings.

Access to information resources was essential throughout the project. The university’s online library has been sufficient for literature sourcing. Clinical information and context were provided by the clinical contacts collaborating on the project.

Usability testing participants and clinicians were required to evaluate the application and test the hypothesis. Clinician input was readily available throughout.

3.5. Timeline

Work towards the dissertation officially began around May, though much of the development was completed earlier, through both the research proposal and development for the customer. A Gantt chart for the actual project timeline is shown in Figure 3-1.

Task Name	Duration	Start	Finish	Predecessor
Initial planning and design	**8.13 days**	**21/10/20**	**02/11/20**	
Project introduction meeting	1 hr	21/10/20	21/10/20	
Initial trial search design + wireframes	8 days	21/10/20	30/10/20	
Meeting: review design	1 hr	02/11/20	02/11/20	3
Regular progress meetings	311.13 days	06/11/20	17/01/22	
Design and Development	**335.13 days**	**09/11/20**	**21/02/22**	
Ongoing design and development	69 days	09/11/20	11/02/21	4
Demo: stakeholder and supervisors	1 hr	02/02/21	02/02/21	
Work paused - interrupted studies	199 days	12/02/21	17/11/21	18
Meeting: resuming work	1 hr	18/11/21	18/11/21	20
Ongoing design and development	8 wks	18/11/21	13/01/22	21
Demo: Morriston Hospital Urologists	1 hr	17/12/21	17/12/21	
Demo: Patient Involvement + funders	1 hr	21/02/22	21/02/22	
Develop and write research proposal	4 mons	14/12/21	03/04/22	
Top up research proposal sections	40 days	04/04/22	27/05/22	
Adjust and complete introduction	2 wks	04/04/22	15/04/22	
Adjust and complete literature review	2 mons	04/04/22	27/05/22	
Adjust and complete methodology	4 wks	04/04/22	29/04/22	
Data gathering and dissertation completion	**73 days**	**30/05/22**	**07/09/22**	
Develop UX test scenario	2 wks	30/05/22	10/06/22	26
Trial UX test scenario	2 wks	13/06/22	24/06/22	31
Tweak UX test scenario	3 wks	23/06/22	13/07/22	31
Conduct UX testing	5 wks	14/07/22	17/08/22	33
Adjust methodology to reflect changes	3 wks	14/07/22	03/08/22	33
Adjust site based on UX testing results	2 wks	18/08/22	31/08/22	34
Write results, discussion, evaluation, and conclusion	2 wks	18/08/22	31/08/22	34
Final adjustments to dissertation	14 days	18/08/22	06/09/22	34
Submit MSc dissertation	1 day	07/09/22	07/09/22	
Viva	**18 days**	**18/08/22**	**12/09/22**	
Prepare MSc viva and demo	18 days	18/08/22	12/09/22	34
Present MSc viva	1 hr	12/09/22	12/09/22	

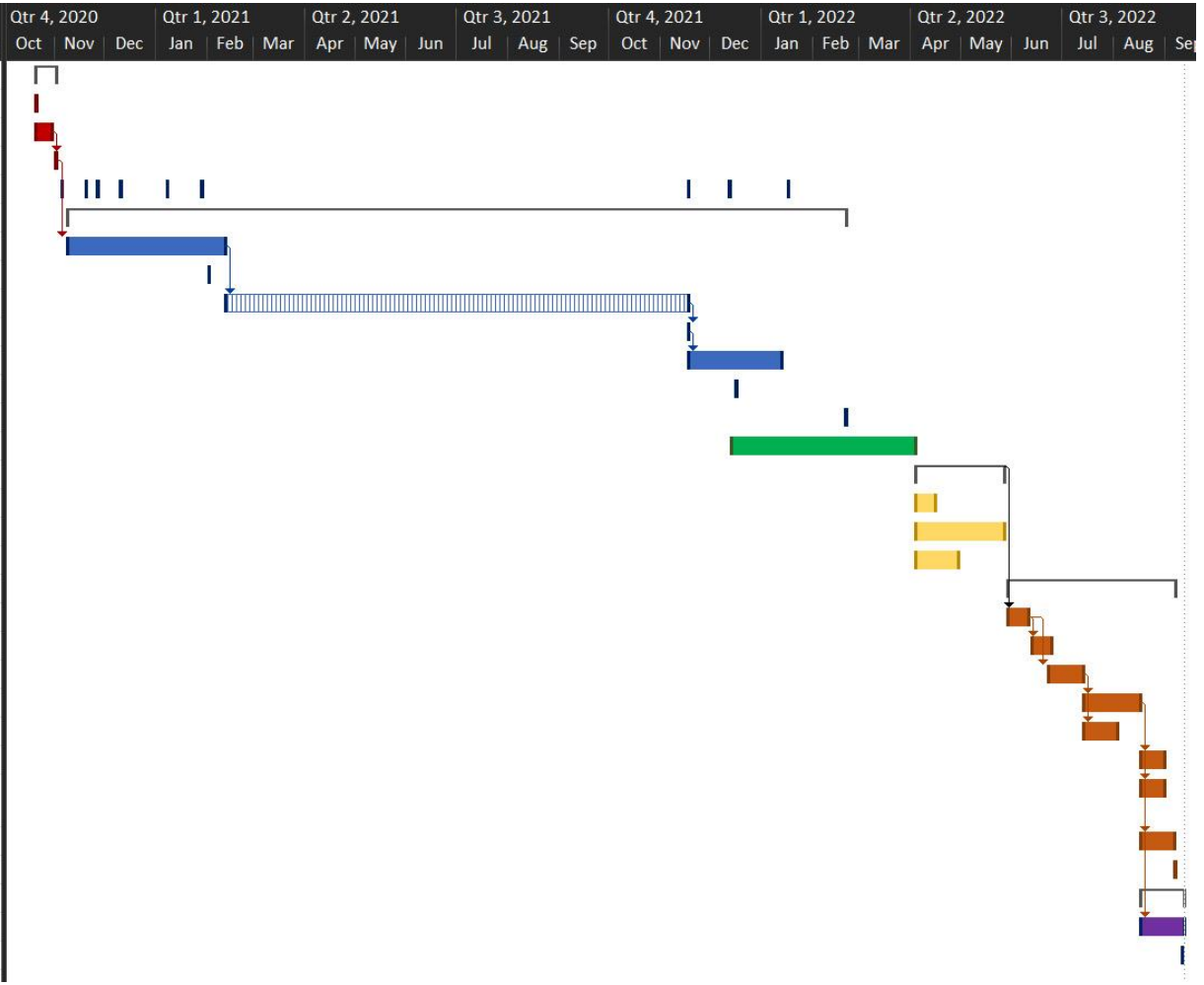


Figure 3-1: Project timeline Gantt chart

3.6. Risks, Ethics, and Encountered Difficulties

This work had both generic and project-specific risks associated with it. The primary risks specific to this project were clinicians withdrawing due to funding withdrawal, and difficulty in acquiring UX testers. Funding withdrawal would likely not have affected the academic aspect of this work. Clinician involvement was closely monitored, while the project was kept relevant to them. The project could have continued without clinician feedback, though this would not have been ideal.

There was some difficulty acquiring usability testing participants, potentially due to prospective participants' understandable discomfort or uncertainty about interviews and involvement in research. The timeframe to undertake usability testing was shorter than ideal due to personal circumstances, however, this difficulty was mitigated through planning and arranging interviews in advance where possible. The usability testing contained medical topics which some participants could find upsetting, as a result of searching for and discussing trials for various illnesses. This concern was alleviated by prefacing interviews with verbal and written disclaimers and consent indications. The survey was configured to be completed anonymously, to avoid ethical complications. Furthermore, all participants were at least 18 years of age. When testing the site, participants were informed that the trial data had been adjusted from real trials, to suit the usability testing.

Generic risks to this project primarily consisted of requirements inflation, overrunning the timeframe, and student or supervisor absence. Requirements were closely reviewed with clinicians and the project supervisor. Additional requirements would have affected the commercial aspect of the project, while academic work would be unaffected. Timeframe concerns were managed by closely monitoring progress with the project supervisor to ensure continuous progress. Remaining ahead of the timeline where possible provided a buffer, negating many effects of time loss due to any short periods of illness or other absences which occurred. Absence due to severe illness significantly altered the project timeline, although an interruption of studies controlled this. Detailed project notes were kept prior to absence, particularly regarding literature review progress, which simplified resuming work. Legal and reputational risks to the university and researcher were a possibility, though unlikely, and were

continuously monitored. As there was no involvement with patients or at-risk groups, this risk was minor.

3.7. Section Conclusion

This section has discussed research and development methods, including associated factors such as ethical concerns, risks, and the project timeline. Methods consist primarily of software development and usability testing, supported by a literature review and unstructured interviews. The following section describes the software design and development processes, and justifies design decisions.

4. Software Design and Implementation

This section describes the key processes and decisions made during the design and implementation stages, together with justifying the approaches taken.

In addition to the development of a web application, a CT pro forma was created, with clinician input, to be completed by CT research leads wishing to add their trial to the site. This form is included in Appendix C.

4.1. Application Requirements and Purpose

The web application's requirements were ongoing, dependent on the previous progress and discussion within the Urology department. These stakeholders developed requirements over time, hence the development being both incremental and iterative. The application was developed to increase patient agency and independence, also facilitating research data collection. Development undertook a primarily iterative, feature-by-feature approach as highlighted in Section 3.3**.** The application was segmented into a patient portal for accessing trial information, and a clinician portal for managing this information.

The requirements are summarised using a Gantt chart in Figure 4-1, and detailed extensively in Appendix D, along with implementation timeframes. Feature order and implementation timeframes are based on version control commits.

Task Name	Duration	Start	Finish
Start - add trial search form, trial results list, individual trial pages	8 days	21/10/20	30/10/20
Add staff home, manage trial staff pages (summary list, crate, view/edit, delete)	5 days	26/10/20	30/10/20
Add manage clinical trials (summary list, crate, view/edit, delete)	7 days	30/10/20	09/11/20
Trial search changes: add sub-specialties step, create dedicated home page	10 days	09/11/20	20/11/20
Trial search changes: add keyword search step and search synonyms	6 days	20/11/20	27/11/20
Add eligibility criteria: patient trial view should display list of criteria as list	7 days	27/11/20	05/12/20
Eligibility criteria changes: criteria should instead be step-by-step form	8 days	05/12/20	15/12/20
Add search logs: track search inputs and results, for staff to view	8 days	05/12/20	15/12/20
Trial search changes: add medical condition step, and ti trial and clinician records	10 days	15/12/20	26/12/20
Increased data privacy: anticipating moving from prototype to deployment, add privacy policy	10 days	02/01/21	14/01/21
Search logs changes: should also contain number of trials clicked, and if an eligible trial was found.	7 days	02/01/21	09/01/21
Trials and search changes: trials need location field. Make condition compulsory and keywords optional	3 days	14/01/21	18/01/21
Trials changes: need additional specialty for research nurses. Each trial associated with a research nurse	7 days	18/01/21	26/01/21
Add patient feedback survey: form with yes/no questions in popup on trial page	7 days	18/01/21	26/01/21
Trial page changes: should display contact details of Principal Investigator and secretary	6 days	26/01/21	02/02/21
Patient feedback survey changes: move survey to its own page, linked to by popup	2 days	02/02/21	03/02/21
Trial changes: allow staff to upload related files with descriptions, display to patients	8 days	02/02/21	11/02/21
Off ill - development paused. Noted here as it affected development timeline	199 days	12/02/21	17/11/21
Add trial saving: patients can save eligible trials, to be visible on dedicated page. Can be ranked	11 days	18/11/21	02/12/21
Add contact staff: patients should be able to send their details to a trial's contact point, if they are eligible	28 days	02/12/21	10/01/22

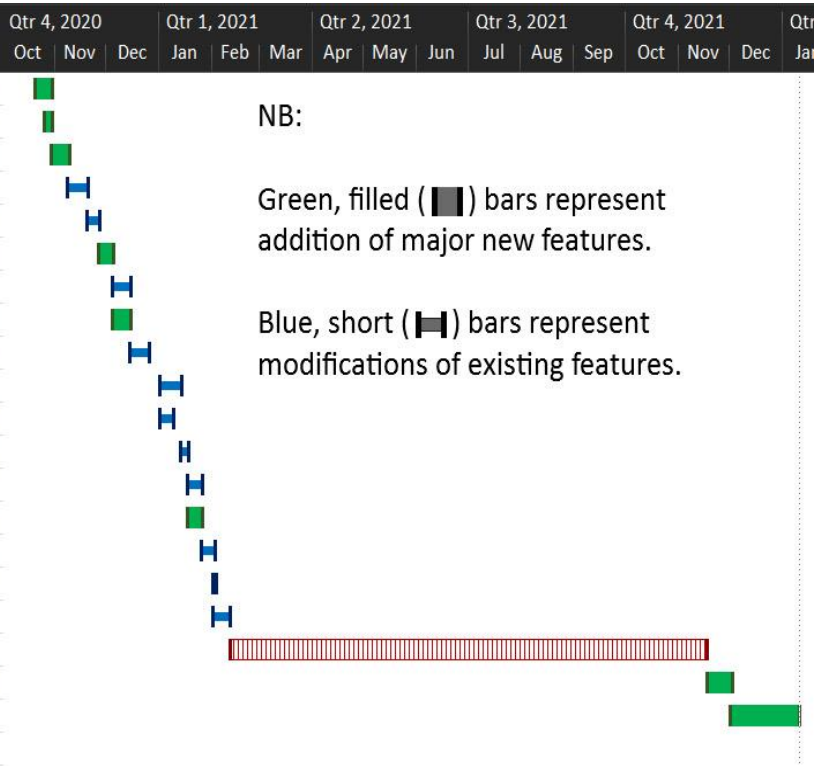


Figure 4-1: Requirements summary Gantt chart

4.2. Application Design

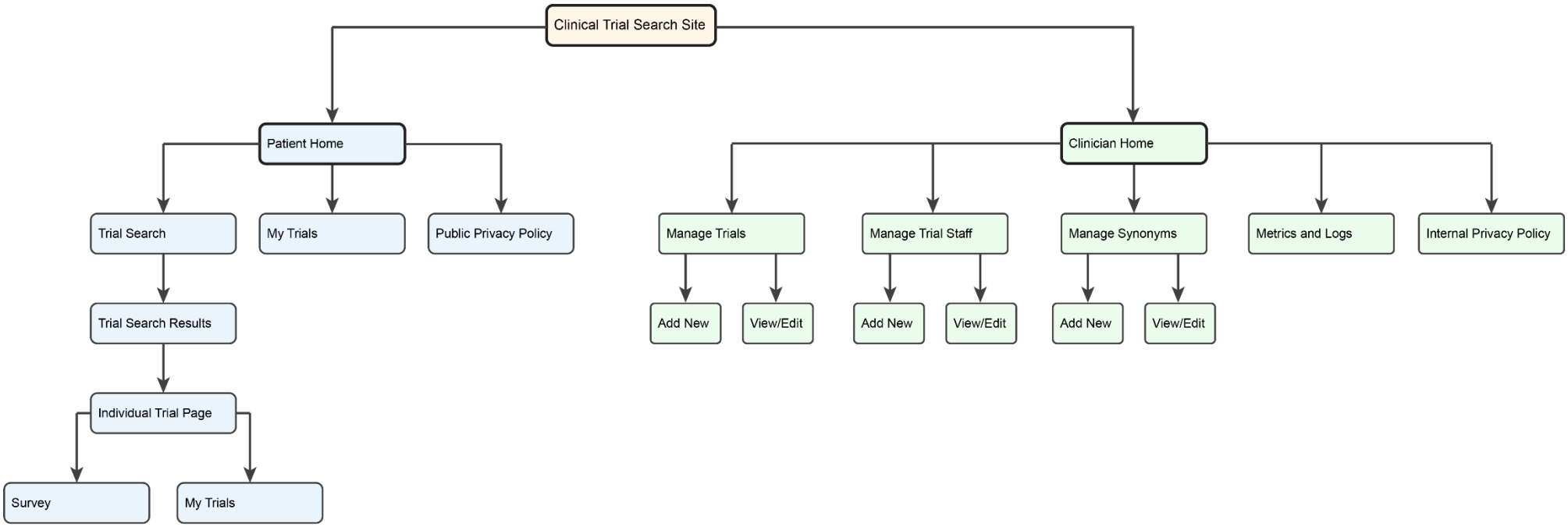
Application design entailed creating a website hierarchy, mapping functionality to individual pages, designing individual pages, and database design to facilitate the complex links between different types of data.

4.2.1. Website Interface and Functionality

The site is split into two portals. The staff portal is aimed at clinicians, managers, and data entry staff. The patient portal is the public, front-facing interface of the system. A site map is shown in Figure 4-2, highlighting not only the links between each page for both patient and clinician portals, but the patient journey when searching for CTs. To increase the ease of use of the system, no accounts are required to use the patient portal.

Design took a mobile-first approach – content was designed for mobile devices, and expanded to fit larger displays. Accessibility was a priority – the design stage took into consideration guidance and implications of the Web Content Accessibility Guidelines (WCAG) 2.1 [83]. Colour contrast was a primary focus, as this involved modifying existing libraries.

Page wireframes were prototyped in Adobe Illustrator for stakeholder review. After discussion and applying any adjustments as necessary, designs were finalised in Adobe Xd, before being implemented using HTML and CSS. An example of a final page design, for the Clinician's View/Edit Term page is shown in Figure 4-3.



NB for Patient Portal:

Trial Search, My Trials, Patient Home, Survey, and Public Privacy Policy pages are accessible from all pages via the navigation bar.

NB for Clinician Portal:

Manage Trials, Manage Trial Staff, Manage Synonyms, Metrics and Logs, Clinician Home, and Internal Privacy Policy pages are accessible from all pages via the navigation bar.

All pages are preceded by a login page if the browser is not already logged in.

Figure 4-2: Site map

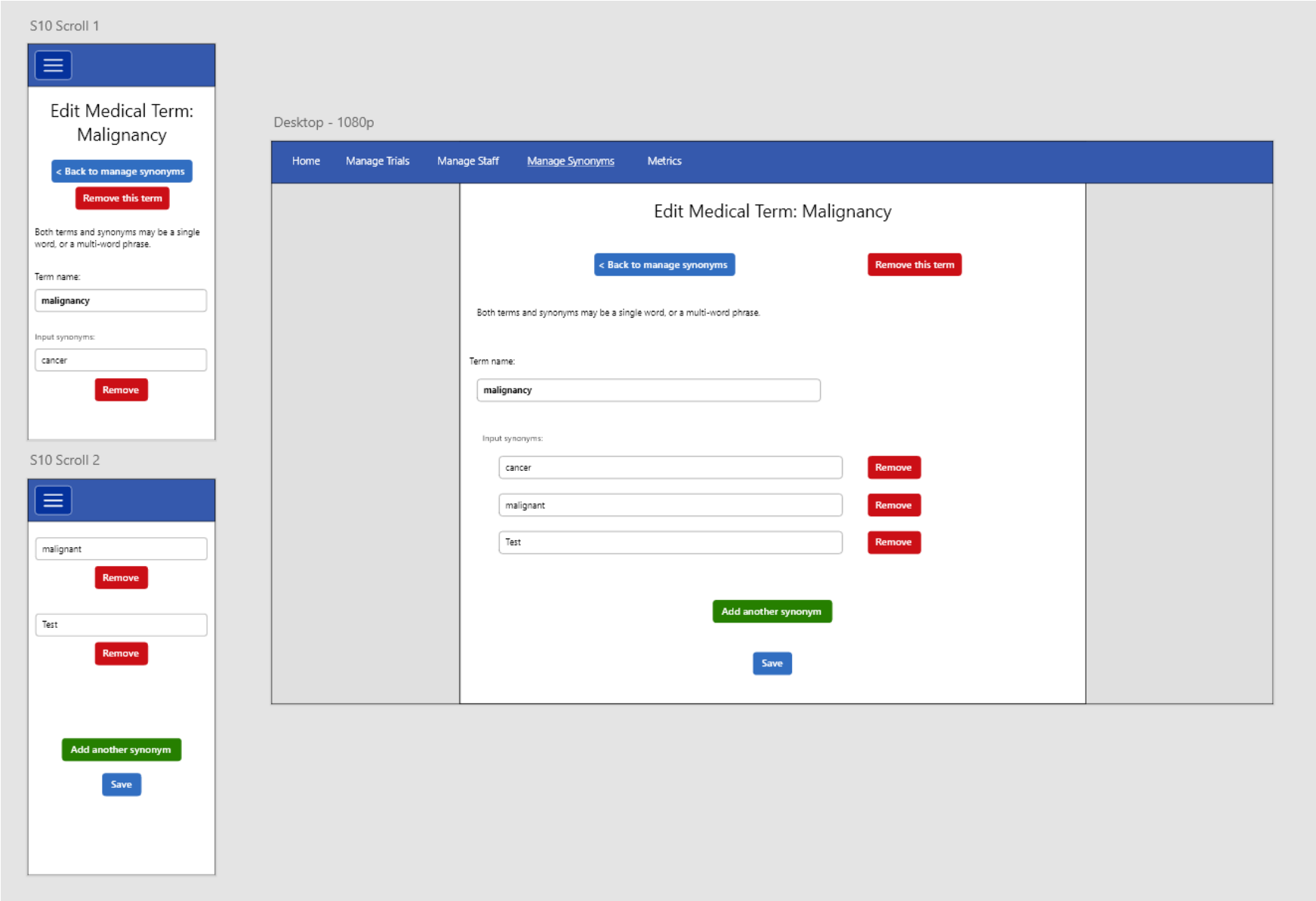


Figure 4-3: Adobe Xd wireframe example: Edit Term staff page

4.2.2. Relational Database Design

One of the most significant challenges of this project was database design, due to its complex, relationship-heavy nature. The final database features 24 entities, with extensive relationships, facilitated through nine associative entities. Both the patient and clinician portals access the same database due to the significant amount of shared information.

The core site functionality relies on a set of tables for trial information, including associated files, staff, eligibility criteria, and medical conditions. A set of tables facilitates trial search logs, allowing stakeholders to review the system's usage. This includes tables for specific condition and keyword searches, along with the responses to individual questions from a feedback survey. An accounts table stores login credentials for staff who edit the site. Keyword search synonyms are facilitated by a medical term entity, which may be associated with multiple synonym entities.

A summary Entity Relationship Diagram (ERD) of the site database, using crow's foot notation, is shown in Figure 4-4. Further detailed ERDs are included in Appendix E.

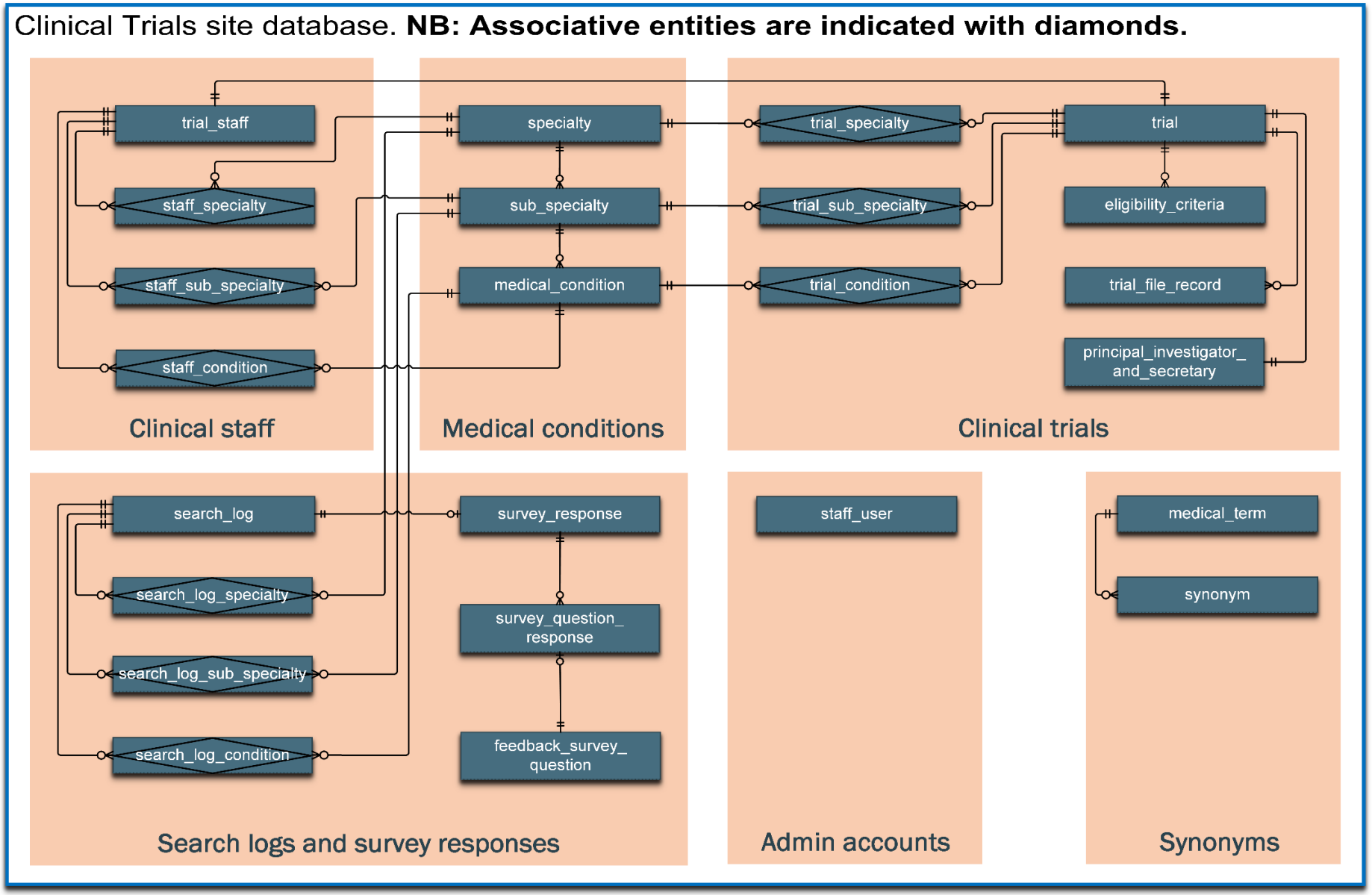


Figure 4-4: Database Entity Relationship Diagram (ERD)

4.3. Application Development

The site is based on the PHP server-side programming language. This language was used due to its compatibility with MySQL and the PhpMyAdmin database management tool. Additionally, it is familiar from previous development projects. The core database access code was implemented using Object-Oriented Programming (OOP) and the PDO class within PHP. The primary implemented database class, *DatabaseAccess*, features data cleaning methods, primarily to prevent SQL injection, and converting raw HTML input into HTML entities as a security measure. This class features database access for data which is common between the clinician portal and the patient portal, such as trial data. The *PatientDatabaseAccess* and *StaffDatabaseAccess* classes inherit from the base *DatabaseAccess* class, and extend its functionality for patient- or staff-specific data, respectively. The remainder of the site's PHP code is function-based. OOP was not beneficial for most pages as they have unique implementations found nowhere else on the site, and PHP's associative arrays were more appropriate. The PHP password hashing feature was incorporated to store passwords securely in the MySQL database.

The Asynchronous JavaScript and XML (AJAX) method was used to dynamically update website content via the HTML Document Object Model (DOM). This was facilitated via the jQuery JavaScript library [104]. Usability was at the core of this application, and AJAX aided this by making pages simpler to use and more interactive, especially for custom forms. JavaScript modules were created to mitigate code duplication where some pages re-used JavaScript functions. This code was primarily event-driven.

The Bootstrap 4 framework [105] was adopted for its grid system and consistent styling, although a significant amount of custom CSS development was required. Bootstrap facilitated a mobile-first, responsive design. Some core components of Bootstrap were modified, as they did not meet the WCAG 2.1 AA standard for colour contrast. This limitation within Bootstrap is acknowledged by its creators [106], who recommend that developers modify the library to meet accessibility requirements. The FontAwesome 5 icon library [107] was incorporated to improve aesthetic appeal and user experience.

The PHPMailer library [108] was used to facilitate patients contacting a trial's contact point via email if they are considered joining it, or wish to find out more about a trial. A base HTML file was created with placeholder values, to be algorithmically replaced prior to being emailed. A form was implemented, allowing patients to provide their contact details, and indicate their interest in a trial. A "send to contact point" button facilitated this by triggering an email to be sent.

Markup and stylesheets were validated against their specifications using the W3C Markup Validation Service [109], and W3C CSS Validation Service [110], respectively. Additionally, styles were prefixed for all modern browsers using Autoprefixer CSS online [111]. Accessibility was evaluated using the aXe Chrome extension [112]. Functionality and CSS breakpoints were tested across each page of the site for the two most recent major versions of Chrome, Edge, and Firefox on Windows 10, and the most recent version of Chrome and Firefox on Android 10. Regrettably, an iOS device was not readily available to test Safari compatibility. Ideally, BrowserStack [113] would have been used for browser testing across a wider range of browsers, however, this tool was not available.

Cookies facilitated site functionality. The site's cookie policy was implemented on advice from the Information Commissioner's Office (ICO), particularly regarding cookies which were "strictly necessary" – essential to the site's core functionality [114], [115]. The cookies used on the site are detailed in Table 4-1.

Table 4-1: Site cookies

Cookie Name	Essential?	Description
PHPSESSID	Yes	Part of PHP functionality, primarily used to remember that a browser is logged in.
cookie-consent	Yes	Used to remember cookie consent decision, prevents further privacy policy popups.
trials-emails-sent	Yes	Used to remember which trials (by ID) a browser has sent contact emails for. Prevents spam-emailing clinicians.
research-consent	Yes	As with cookie-consent, but specifically for participant consent to usability testing. Not applicable to production site.
interested-trials-json-cookie	No	Saves trials for patients as a bookmarking feature, along with their contact details, to send to trial contact points.

4.4. Section Conclusion

This section has described and justified the design and development approaches taken, and summarised the final software deliverable. The following Section describes the data gathered through using the site as a research tool, and discusses the findings and implications.

5. Results and Discussion

This section describes and discusses research results and implications. Data included usability testing, Urology clinician feedback, and PPI feedback. The primary focus of this research was the usability evaluation. These data test the hypothesis and provide feedback for the commercial aspect of this work.

5.1. Usability Testing

Usability testing outcomes were largely positive, with few exceptions. 33 participants carried out a combined interview and survey. 15 and 18 participants tested the site on mobile and desktop devices, respectively, due to the availability and familiarity of devices by participants. Outcomes were positive regardless of the device used to undertake the testing. Interview medium was also imbalanced, with 11 participants conducting the evaluation via a video call, while sharing their screen, while 22 participants conducted it via an audio-only call. This affected observation, although the significance of this is limited by the overall strong usability performance.

The participant sample was determined by those who were available locally. Brief descriptions were used to describe technical ability/literacy, and participants were asked to choose which they felt best described them. The balance was as follows, listed by response count and percentage:

- **(4, 12.1%)** Infrequent user: I don't use phones or computers often
- **(13, 39.4%)** Fair: I can use a phone/computer for basic tasks such as checking emails and browsing the web
- **(12, 36.4%)** Proficient: I use computers frequently for a range of tasks (such as work), with little difficulty
- **(4, 12.1%)** Expert: I work or study in IT

This distribution is probably reasonably representative of the general population, indicative of a wide range of technical abilities, with few extremes [116]. This range of technical abilities increases generalisability, although this is limited as it is self-reported.

5.1.1. Usability Interview Observations

Observation was limited due to social distancing precautions. For participants who did not share their screen, verbal conversation was used as a limited observation form. Nevertheless, several key observations were made throughout the testing, which could not have easily been determined through surveys.

Participants' devices could not be controlled, due to the remote approach. A range of factors not controlled as a result of this could affect usability, such as device size, operating system, web browser, and internet connection speed. This limitation could be addressed in further testing. However, this factor also increased finding generalisability – a wide range of devices were used, all were participants' personal devices. As such, the participants were most familiar with these devices. Should this system be deployed, patients would be using their personal devices. Thus, this data gained generalisability and validity at the cost of reliability. Additionally, this reinforced the browser testing conducted throughout development. The range of devices in use also exposed a flaw in the website. A specific JavaScript function did not function in the Safari browser. This feature was not critical to usability testing; however, this would not have been discovered otherwise.

Many participants experienced inconvenience when searching for the phone number of a trial's contact point. Many scrolled through the list of contacts, debating whether the appropriate contact for the prostate cancer trial was the "contact point" or the specialist in prostate conditions under the "urology staff" heading. Reviewing the survey responses, almost all participants correctly chose the phone number. Despite this, rectification is needed, which would improve the product and aid patient agency, supporting the hypothesis. Additionally, when participants found a trial which they were ineligible for through the criteria form, when advised to return to the search results page, they attempted to use the "restart form" button to do so. Those who experienced this found the correct actions without assistance, although this took time. These observations suggest that the included patient guide requires expansion.

Some participants voiced difficulty connecting with the patient persona, and that they believed they could not fully appreciate the motivations of the allocated persona. Many participants also anticipated that if they were a patient currently searching for

CTs, they would find the site simpler to use due to the specific nature of the research scenario. These evaluations were conducted in isolation. In reality, patients may have support from family or friends. It is reasonable to suggest that the outcome would have been closer to the hypothesis in a real scenario. Additionally, the Urology scenario appeared to embarrass some participants. This, combined with difficulty connecting to the patient persona, could have affected survey responses.

Several of the instruction points proved unnecessary – participants made assumptions and took these steps in advance. This primarily consisted of navigating to the trial search page, and on completing the search form, exploring trial results on their individual pages. Furthermore, on reaching an individual trial's page, many participants were able anticipate the next instruction – using the eligibility criteria form. This is not reflected in the survey responses. However, it links to the hypothesis, identifying that participants could use the application independently.

Ironically, participants' most frequent difficulty during the testing process was responding to some of the questions on Microsoft Forms. This could have impacted survey responses.

5.1.2. Usability Survey Success Rates

In order for participants to indicate their ability to reach key milestones in site usage, without assistance, three yes/no questions were employed. These questions and their success rates ("Yes" responses) are shown below:

"Were you able to find and use the trial search form, without assistance?"

32/33 (97.0%)

"Were you able to navigate trials and find a trial which you were eligible for, without assistance?"

32/33 (97.0%)

“Were you able to send your details to the trial's contact point and find their phone number, without assistance?”

31/33 (93.9%)

Participants were also asked to find and input the phone number of the eligible trial’s contact point. This information was present on the trial page, and was input into the Microsoft Forms survey. 29 of 33 (87.9%) participants correctly found and input the contact point’s phone number. One participant did not provide a phone number, having also indicated via the survey that they could not make contact with the contact point or find their phone number. The remaining three participants appear to have made typographical errors. Assuming three input errors, the success rate for finding the contact point’s phone number was 32/33 (97.0%). It is possible that many contact phone numbers on the trial page were superfluous; however, this design was intentional, as specified by the customer.

When asked about the overall outcome of using the site, all participants responded with “I found a trial which I was eligible for.” However, previous question responses complicate this result. Two participants responded that they were not able to complete one of the first two steps prior to finding the appropriate trial. Perhaps the question regarding overall outcome, or its possible responses, were not appropriate. The question and its possible responses could have included indicators for “…without assistance”. Based on previous questions, it appears that 31 of 33 participants (93.9%) found a trial which their patient persona was eligible for, without any assistance. The remaining two participants achieved this with assistance. Assistance provided throughout testing was minor.

These questions indicate that the website is accessible and facilitates patient agency. These findings support the hypothesis; however, limitations must be acknowledged. It is possible that a patient demographic group would provide slightly different findings to those of non-patients. Additionally, responses indicate that the site facilitated a level of agency, not necessarily an increase in agency over current trial search methods. Furthermore, it is likely that a future increase in sample size would introduce participants who would not succeed to use or understand the site.

5.1.3. System Usability Scale Results

To preface this subsection, it is noteworthy that one SUS question was modified. Many participants were uncertain about the word “cumbersome” in one statement. This statement was adapted to read “…cumbersome (slow, complicated)…” [117]. This difficulty was also experienced by Bangor et al. [118], who opted to instead use the word “awkward”. This modification may alter the comparability of the data.

SUS data reinforced the success rates. As described in Section 3.2.3, SUS statements alternate between positive and negative phrasing, such as “I thought the system was easy to use,” and “I found the system unnecessarily complex.” As such, the ideal Likert responses would also alternate between agreement and disagreement. This proved to be the case, as is shown in Figure 5-1. This figure shows responses proportionally, where disagreement is plotted as a negative percentage, and agreement as a positive percentage. In this visualisation, -100% denotes all participants strongly disagreeing, while +100% signifies all participants strongly agreeing. Each statement approached these ideal values, highlighting the site’s strong usability, and the likelihood that patients could use this application to achieve its function, increasing their agency. Generally, responses were not neutral, indicating that participants were confident in their responses.

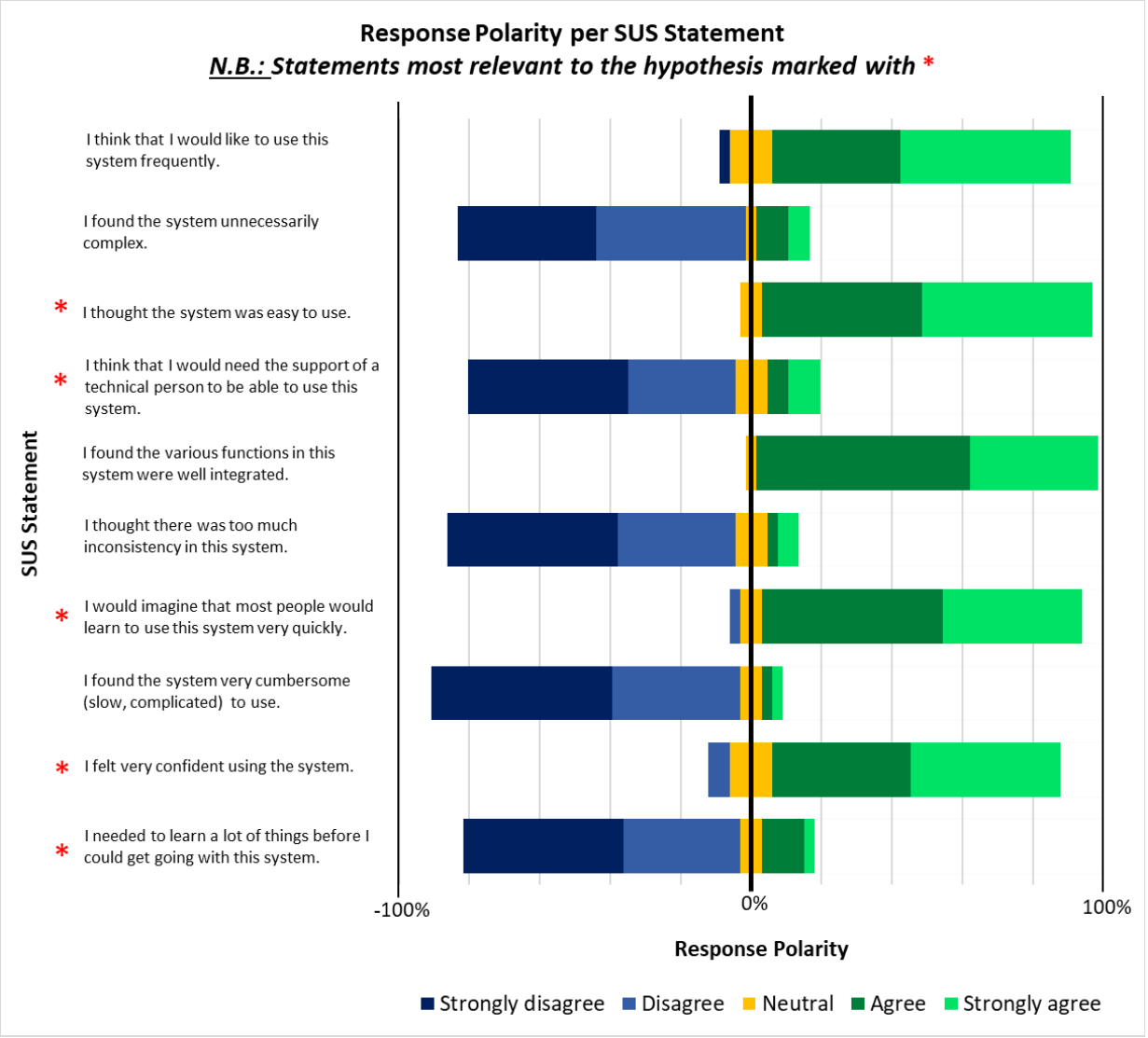


Figure 5-1: Response polarity per SUS statement

When defining the SUS, Brooke cautioned that scores of individual statements are “not meaningful on their own” when evaluating usability. Bangor et al. [118] concur that individual elements of applications cannot be evaluated this way, on account of high correlation between statements. Unlike the work of Bangor et al., this research aims to evaluate a hypothesis, not only overall usability. In this context, SUS statements are individually highly valuable.

Participants largely agreed or strongly agreed (12 and 16 respectively, totalling 84.8%) that the system was easy to use, responding similarly that they felt confident using it (13 agreement, 14 strong agreement, totalling 81.8%). Responses to the latter were similar, with the exception of two participants indicating disagreement. These statements only broadly indicate agency.

Most participants disagreed or strongly disagreed (10 and 15 respectively, totalling 75.8%) that they would need the support of a technical person to use the site. Similarly, most disagreed or strongly disagreed (11 and 15 respectively, totalling 78.8%) that they would need to “learn a lot of things” to use the site. These statements were not as unanimous as those previously discussed. However, they are more directly linked to the hypothesis. The ability of a user to achieve the intended outcome of the site without an expert, or without having to learn very much, indicates a strong sense of agency. However, it is uncertain to what extent this can be generalised to Urology patients in Swansea. Finally, almost all responses agreed or strongly agreed (17 and 13 respectively, totalling 90.1%) that “most people would learn to use this system very quickly.” It is unlikely that the target users of this site would use it on an ongoing basis, as they would no longer need such a resource once enrolled in a trial. Therefore, the anticipation that users would learn to use the site quickly is especially significant to patient agency.

SUS performance is further explored and visualised in Figure 5-2, highlighting positive versus negative responses. Additionally, standard deviations are plotted as error bars. As per Brooke’s initial SUS discussion [89], each of the five Likert responses represents a value from zero to four – “strongly disagree” being zero, and “strongly agree” being four. This chart subtracts the scores of negative statements from four, effectively inverting them, providing an overall outlook per statement. Bangor et al. also took this approach [118]. Therefore, in this graph, zero represents entirely pessimistic responses (i.e., agreeing with negative statements, or disagreeing with positive statements), and four represents completely optimistic responses. This approach was taken to validate responses, given the diversity of the questions. Standard deviations varied, but were generally low. However, positively phrased statements had lower standard deviations than negatively phrased questions, with mean deviations of 0.72 and 1.12 respectively. The reason for this is unclear.

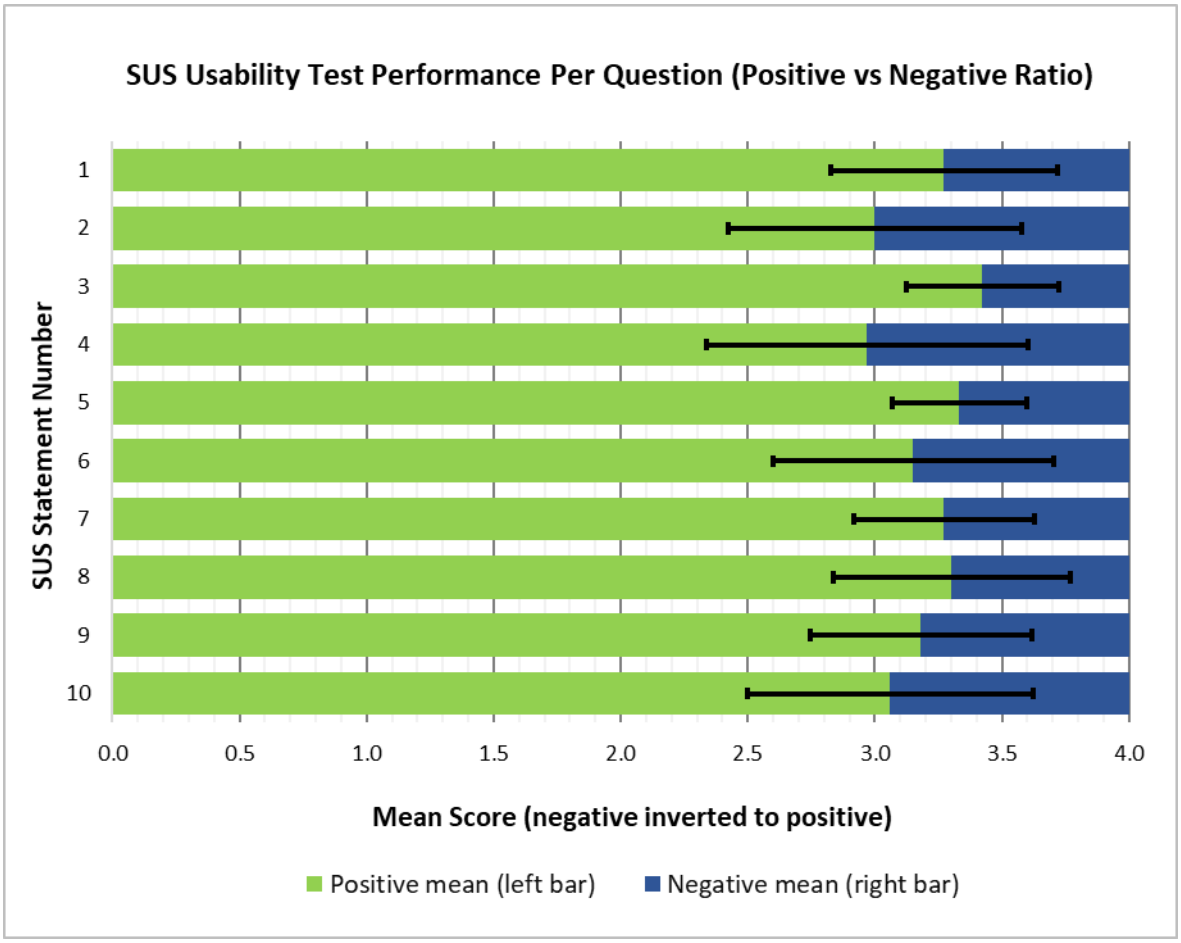


Figure 5-2: SUS outlook per statement (means)

Overall, SUS scores were very strong. The mean score was 79.9/100, and the median was 85.0/100. Scores ranged significantly - from 50 to 100, with a standard deviation of 14.9, as highlighted in Figure 5-3.

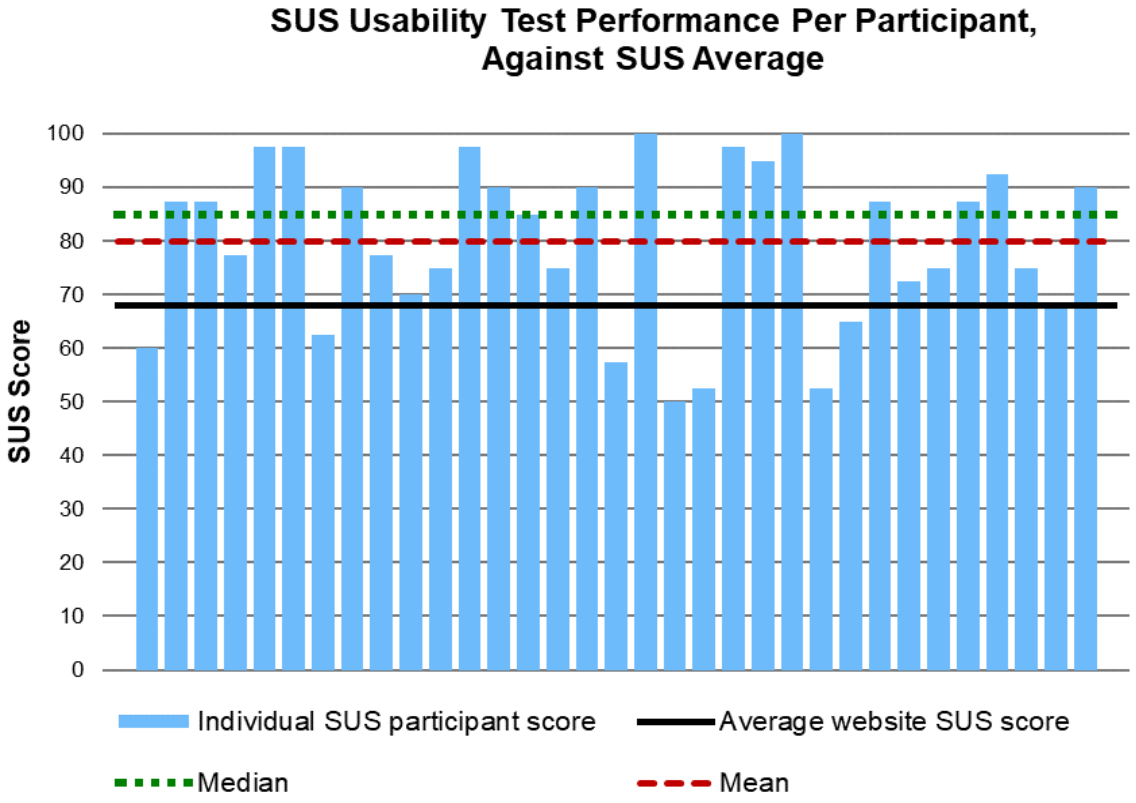


Figure 5-3: SUS scores per participant

Eight participants rated the site below the global SUS average of 68, most by a large margin. In total, four participants considered themselves infrequent technology users, three of whom rated the site below 68. Additionally, six of those rating the site below 68 were in the upper age bands of 55-64 or 65+. Three of eight low-scoring SUS participants made no negative comments in the qualitative questions. The five remaining respondents had few negative comments. Therefore, the direct cause of low SUS scores is uncertain with this sample size.

In 2008, Bangor et al. published data from 2,324 SUS surveys conducted across 206 studies [118]. This paper introduced an experimental adjective rating system based on SUS scores, further described in [119], shown in Figure 5-4. The authors noted the SUS score bias, with responses leaning towards the higher end, and a mean website SUS score of 68. They recommend that “passable” products should score above 70, with “better” products ranging from high seventies to high eighties, and superior products reaching 90. The trials site scored well, however, its wide score

range may suggest that an interface upgrade is warranted. In this format, the developed CT search site would rank between ”good” and “excellent” on their adjective scale, also significantly above their mean reported website score. This indicates that the site facilitates its intended purpose well, although, as the authors noted, high SUS scores do not guarantee acceptability. Furthermore, the similarities and differences in their methodology and sample, and the one undertaken by this project, are not certain.

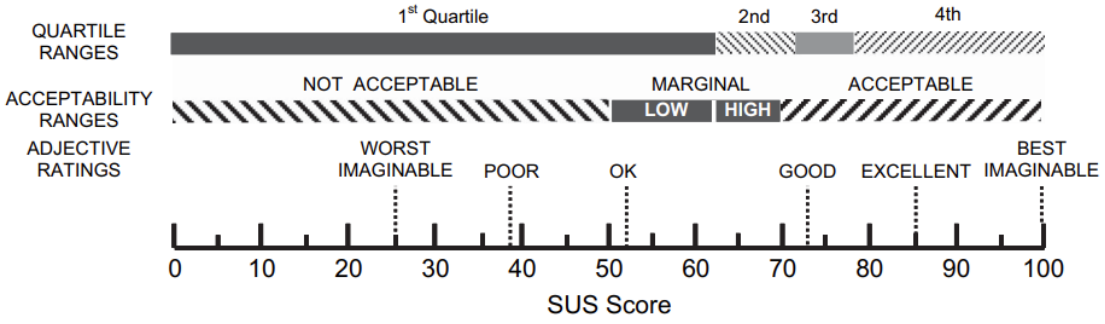


Figure 5-4: Proposed SUS scoring adjectives by Bangor et al. [118]

Based on over 5,000 SUS responses, Sauro provided a percentile ranking system based on SUS scores [120], shown in Figure 5-5. From this scale, the CT search site would rank approximately between the 87th and 96th percentiles, depending on whether the mean or median score was used. This is far more insightful than a mean SUS score as it puts it in context with other sites. However, as noted above, the methodology and way the SUS was administered would impact the percentile rating. As such, this score is indicative.

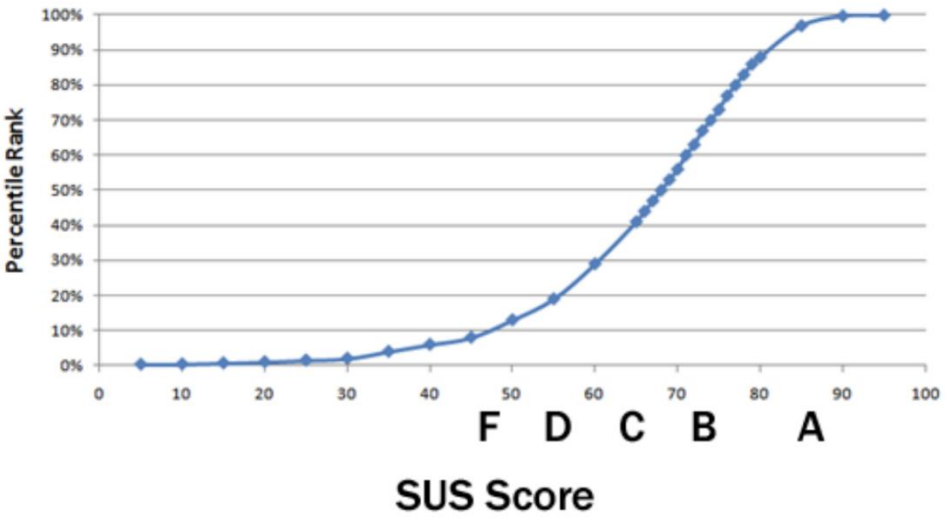


Figure 5-5: SUS score versus percentile by Sauro [120]

5.1.4. Qualitative Response Data

Responses to the four qualitative questions were categorised, providing a high-level overview. Category distributions for these questions are shown in Figures 5-6 to 5-9.

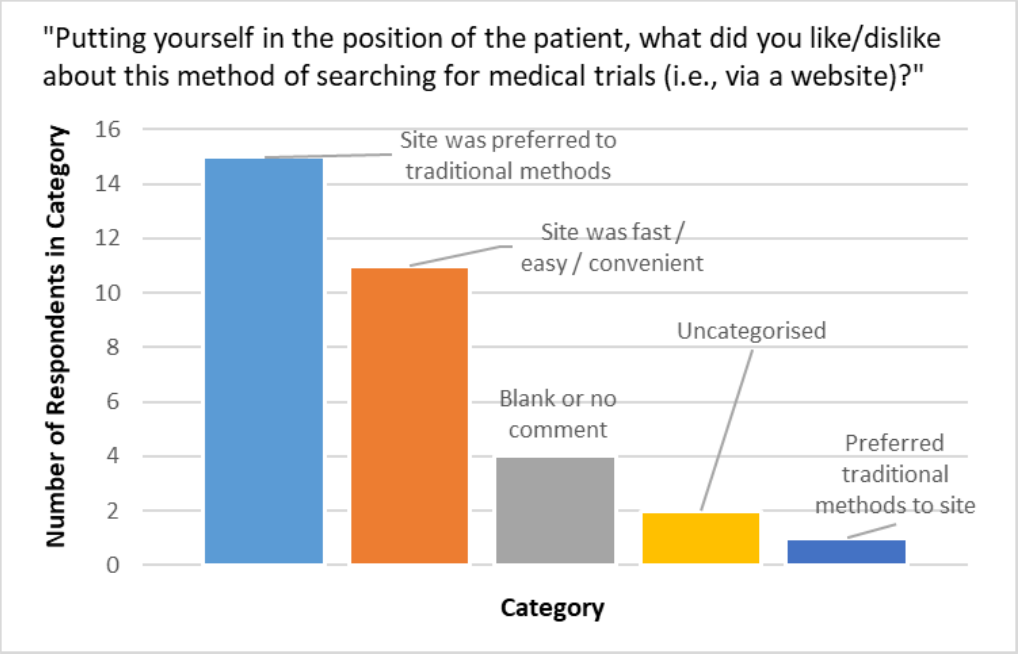


Figure 5-6: Categorised responses to qualitative question 1

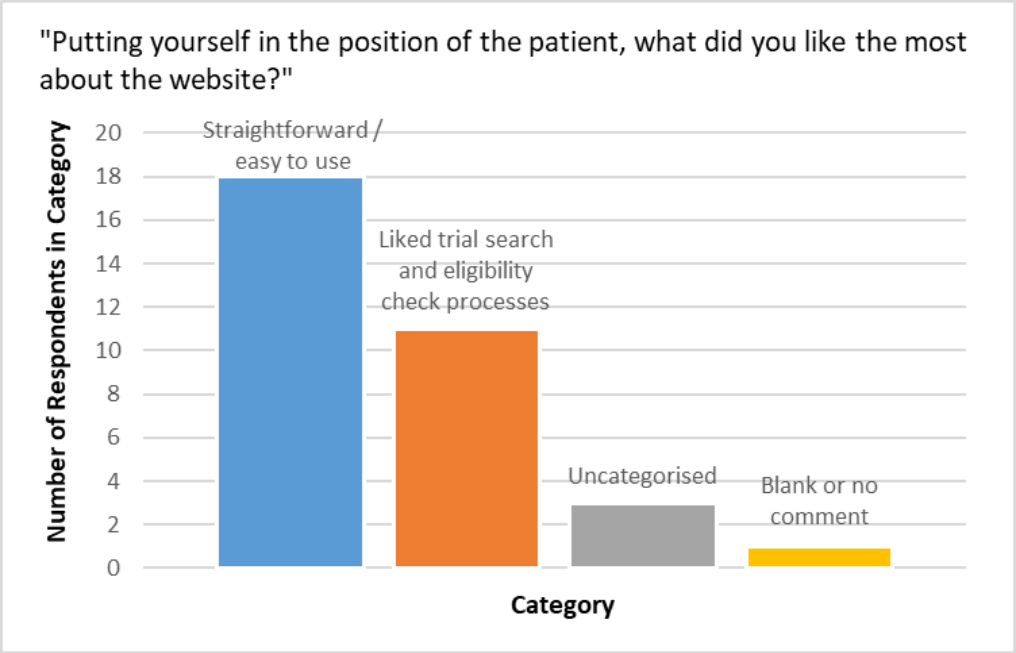


Figure 5-7: Categorised responses to qualitative question 2

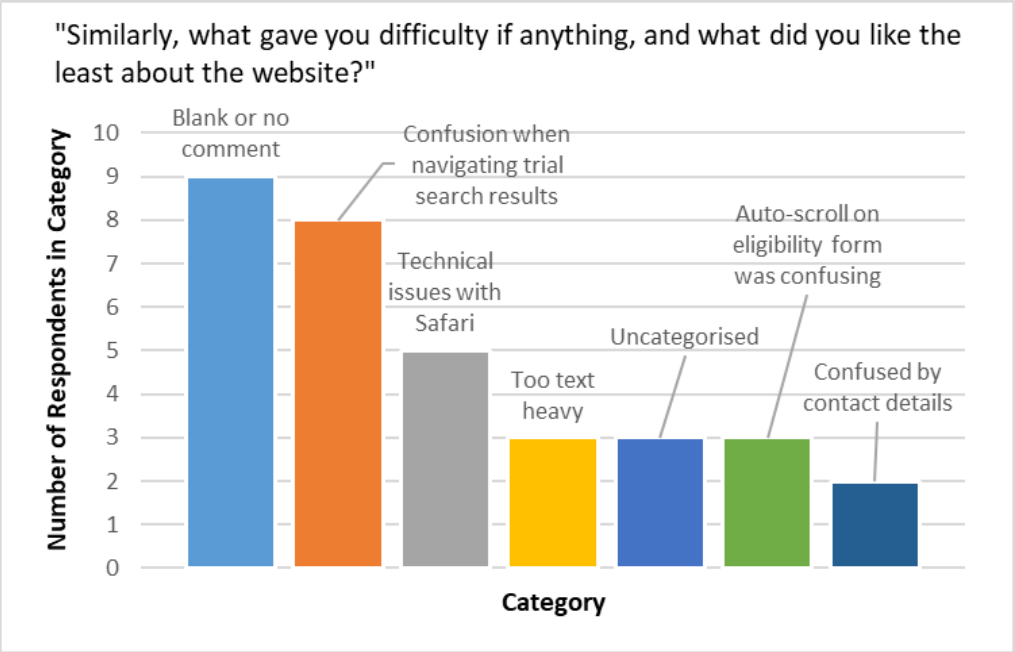


Figure 5-8: Categorised responses to qualitative question 3

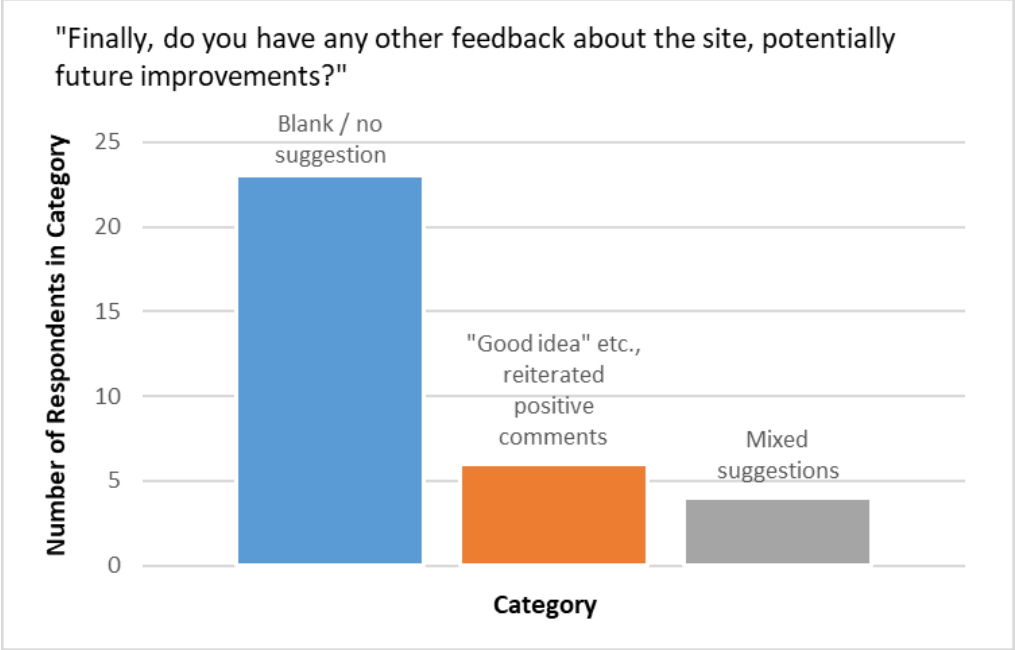


Figure 5-9: Categorised responses to qualitative question 4

When asked about the use of the website as a method of searching for trials, responses varied, but were generally positive. 11 respondents described this method as “fast”, “easy”, “convenient”, or similar adjectives. Furthermore, 15 participants felt that this site would be preferred over traditional methods such as phone appointments or travelling to hospitals for appointments. Participant 25 preferred traditional methods, stating, “I would prefer to go to see a doctor than to use a website”. This is a valid point which should be considered if further resources are allocated to the project. These findings regarding participant preference for a web application over traditional methods are insightful. However, without determining that the same conclusions would be drawn by Urology patients who have already searched for trials using traditional means, the hypothesis is supported, but not conclusively proved. Some examples of responses, particularly highlighting agency, are:

- “did find it a bit difficult but easeri [sic] than travel” (participant 24)
- “liked the privacy/anonymity of looking for a trial myself - and the fact that no doctor/professional with a vested interest could influence my decisions.” (participant 33)
- “I would like to be able to find trials for myself. It would enable me to feel in control of my future” (participant 3)

Similarly, participants were asked “what did you like the most about the website?”. In hindsight, this was too similar to the first question, limiting its usefulness. 18 responses indicated that the site was generally straightforward and/or easy to use, while 11 appreciated the simplicity of the trial search and eligibility checking implementations. One particularly useful uncategorised response was participant 11, saying “…it gave me the privacy that I wanted,” aligning with some findings from the previous question. These findings are more useful to the commercial, deployment scenario, than to proving the hypothesis. This question’s responses suggest the site has a range of usability-facilitating features, although not all aid the hypothesis. The below responses summarise findings regarding search and eligibility forms:

- “The website gives you plenty of choices. The eligibility navigation is easy.” (participant 6)
- “Thr [sic] questions were easy to answer” (participant 9)

- “found various treatments easily” (participant 31)
- “It wasn't too complicated, and had the right amount of content on it.” (participant 4)

Responses ranged dramatically from the question asking for participants' least favourite aspects of the site, or any aspects which gave them difficulty. The most common responses were regarding confusion when navigating between and understanding trial results (eight participants), and small technical issues due to Safari incompatibility (five participants). Further responses stated the site was too text-heavy (three participants) and the eligibility form’s automatic scrolling caused confusion (three participants). Nine responses either left this question blank, or specified they had no comment. Responses to this question neither supported nor refuted the hypothesis. However, they provided feedback for future development, which could aid in proving the hypothesis by increasing usability, and therefore user agency. Here, participant 26 contradicted the response of participant 4 in the previous question, stating “Nothing in particular. But there was a lot of information on the site.” This is an example of personal preference, which could influence future work – however, the site was designed this way in order to meet specified requirements. Some further example responses for this question are listed below:

- “Getting back to the results list when rejected from a trial.” (participant 3)
- “The contacts were quite confusing.” (participant 10)

Finally, participants were asked for any further feedback. 23 responses were blank or specified no suggestions. Six responses reiterated previous positive comments regarding the site, while four responses provided suggestions. Participant 32 commented, “this is a brilliant initiative and one that is really needed,” aligning with the observation of participant 5, saying “…it gives them [patients] some control over treatment pathway.” These indications lean towards the hypothesis, but were made by non-patients. Along with the sample size, this is a limitation of this data.

5.1.5. Demographic Factors and Links with Literature

There was a weak correlation between participants' age group and SUS scores. Figure 5-10 plots the weak but noticeable correlation of r=-0.38. This finding aligns with the literature review, where many authors found technological barriers in older patients, impacting agency. However, the correlation found while evaluating the CTs site was not as strong as indicated during the literature review.

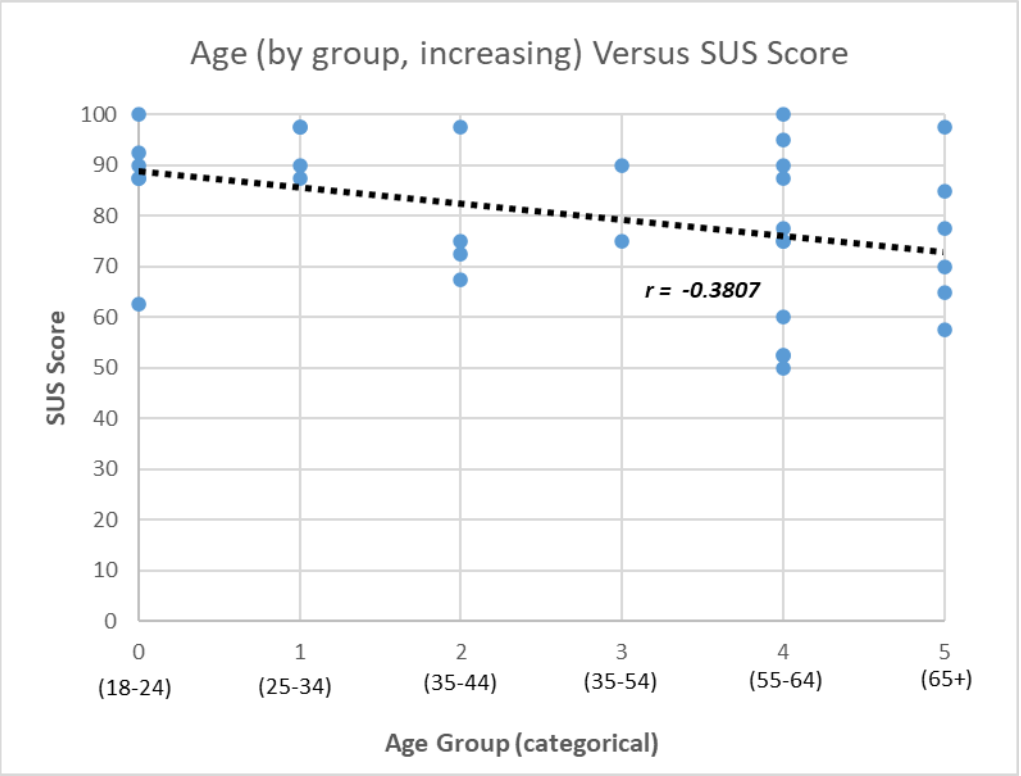


Figure 5-10: Correlation between participant's age group and SUS rating

Unexpectedly, there was only weak correlation (r=0.41) between participants' perceived technical literacy and their SUS rating. Correlation was determined by converting the four categorical options for technical literacy to integers, as they were linearly increasing. Those who considered themselves more technically literate tended to rate the site higher using the SUS, although, by a smaller margin than anticipated. This correlation is highlighted in Figure 5-11. It is possible that the overall high usability of the site, along with its lack of advanced, complex features, contributed to the more evenly distributed SUS scoring. Furthermore, the self-assessed nature of the technical ability/literacy question may not reflect participants' actual ability/literacy, thus skewing

the correlation. However, technical literacy categories also contained explanations, to alleviate this (shown in Appendix B). It would be reasonable to assume that those who considered themselves more technically able also had higher expectations of the site. This may have affected the results. Technical literacy concerns were acknowledged by numerous papers in the literature review, however, this requires further exploration in future reviews.

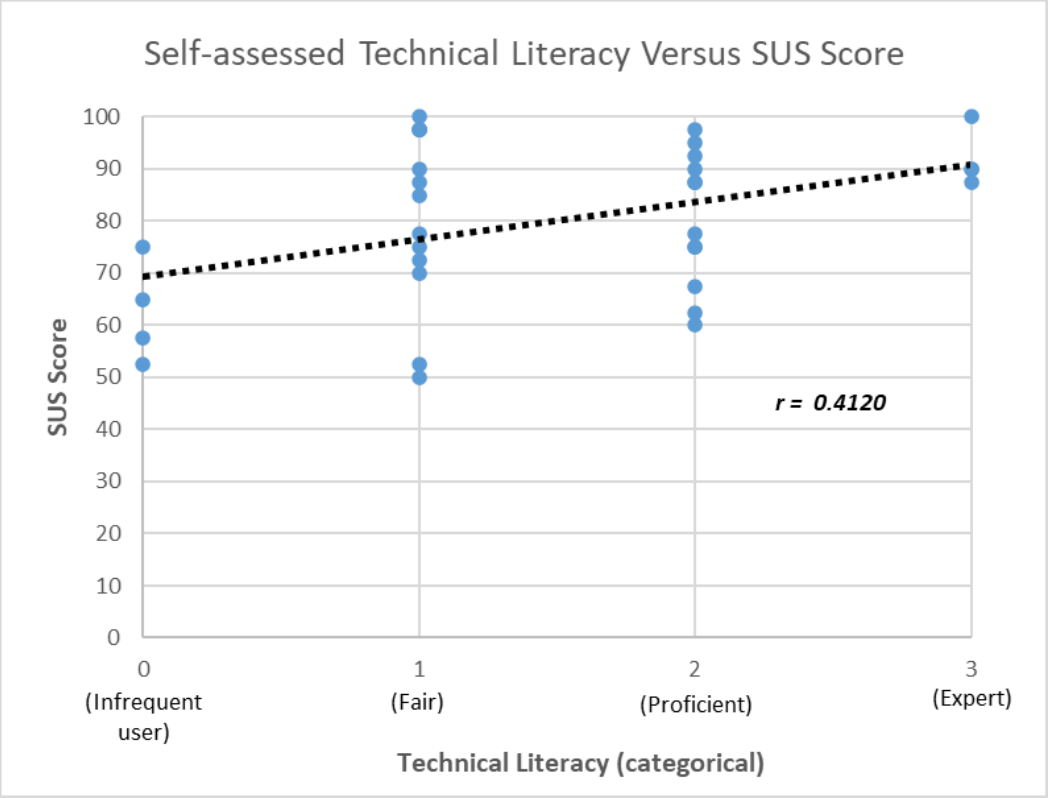


Figure 5-11: Correlation between participant's perceived technical literacy and SUS rating

Two participants disclosed having disabilities relevant to website usage, both of whom rated the site above the mean and median SUS score. However, to be conclusive, this requires a significantly higher sample count. Furthermore, additional research would benefit by including this area into the literature review.

Table 5-1 categorises SUS scores by device type. Notably, those conducting the evaluation on desktop devices rated the site higher than mobile users, with means of 83.5 and 76.9, respectively. Despite mobile users rating the site worse overall, some of the highest scores were from this group. This factor could be due to the varying layouts of the site, however, it conflicts with the mobile-first design approach taken.

Table 5-1: Desktop versus mobile SUS scores

	Desktop (laptop, PC etc.)	**Mobile (phone, tablet etc.)**
SUS Scores	60.0	77.5
	87.5	62.5
	87.5	77.5
	97.5	70.0
	97.5	75.0
	90.0	97.5
	90.0	85.0
	75.0	57.5
	90.0	100.0
	52.5	50.0
	87.5	52.5
	87.5	97.5
	92.5	95.0
	67.5	100.0
	90.0	65.0
		72.5
		75.0
		75.0
Mean	83.50	76.94
Median	87.50	75.00
SD	13.03	15.69

5.2. Urology Demonstration and Continuous Feedback

Continuous feedback was facilitated throughout development, during regular progress reviews and requirements discussion. Additionally, the site was demonstrated to the Morriston Hospital Urology team, who collectively formed the primary stakeholder. These discussions generated and managed the product backlog, which was divided into sprint backlogs.

This approach enabled the Urology stakeholders to engage with the development process and provide clinical input. With the contextual insight provided by clinicians, the site was deemed to meet the requirements and aims, and expected to facilitate patient agency. Clinician suggestions for the site are included in Appendix F.

5.3. Funding Body and Patient Involvement Demonstration

The site was also demonstrated to the NHS Wales Health Collaborative group, and PPI representatives. Similarly to the clinician feedback, this provided contextual input. This feedback also included experienced patient involvement representatives' views, which were more indicative of patients' needs.

This feedback was beneficial, and enabled modifications to the site which would further facilitate patient agency. Some feedback incorporated significant additions or changes, and as such were delegated to future work. A summary of this feedback is included in Appendix G.

5.4. Site Modifications Based on Results

The site was modified based on feedback from usability testing and demonstrations. Within the scope of this research, only minor changes were required based on feedback, primarily consisting of site behaviour and the order of content. Some of these changes, particularly regarding contact information, are likely to increase patient agency when using the site. The changes are listed and shown in Appendix H.

5.5. Limitations

There are a number of limitations to this data which must be acknowledged. These are primarily related to the limited timescale of this project's data collecting component.

Firstly, the usability sample was small, at 33 participants. While the SUS can achieve reliable results with 8-12 participants [121], a small sample size may not be conclusive. Furthermore, this research does not rely solely on SUS scores. Additionally, the participants were obtained through a research call in the local area. This introduces the possibility of a geographical limitation which may decrease generalisability. Participants' devices could not be controlled, which was a limitation, but also improved generalisability. Only one third of interviews were conducted with screen sharing, limiting observation.

Participants may also not be entirely representative of patients. Although there is an inherent level of generalisability between these two groups, the extent of this is probably limited. Ultimately, some users will struggle to use an application so the site should be as accessible as possible.

The website was evaluated when containing limited information as a measure to maintain reasonable interview durations. There were few trial options on the site, and all participants adopted the same patient details. While this increases reliability, it is a narrow approach to testing. In future work, multiple sets of patient details could be compiled, to evaluate the system more broadly.

Feedback from the Urology clinicians and PPI representatives was primarily used to evaluate the development portion of this work. From a research standpoint, this feedback was limited. Only clinicians' views within the Urology department in Morriston hospital were represented. It would be reasonable to assume that clinicians across other hospitals, or different departments within the same hospital, would have different views. However, this feedback benefitted the commercial component as these clinicians collectively formed the customer.

5.6. Section Conclusion

This section has described data gathered throughout the research. This data was discussed in relation to the hypothesis and the aim of the project, indicating its outcome. The following section evaluates and concludes the project.

6. Evaluation, Future Work, and Conclusions

This section evaluates the project from both research and development perspectives. Future work is included, highlighting possibilities for increased breadth and depth of this work. Finally, this section draws conclusions from the dissertation.

6.1. Evaluation

This research incorporated the development of a software application to both meet clinical requirements and to test a hypothesis. The application was developed with continuous feedback from the Urology department at SBUHB, facilitating changes to requirements.

6.2. Evaluation Overview

Through two demonstrations with clinicians and patient involvement representatives, the web application was determined to meet the clinical requirements. As such, some research objectives were also met. The site was evaluated by 33 participants from the local area, and was found to be usable, accessible, and to facilitate agency when searching for clinical trials. A wide range of feedback was received, providing data points and suggestions for future work. The SUS and progress monitoring questions further proved the site to facilitate user independence. As highlighted in Section 5, five statements were especially relevant to the hypothesis. These were analysed and their responses indicate a high level of agency among participants.

The software deliverable of this research is a web application consisting of two portals – one for patients, and one for management by clinicians. The primary purpose of the application is to allow patients to search for CTs matching their medical condition(s), check their eligibility, and make contact with clinicians once interested in joining a trial.

6.2.1. Evaluation Against the Aim, Objectives, and Hypothesis

Overall, the aim of this project was met. A web application was developed with continuous feedback from the Urology team to meet their requirements. Both the clinicians and funders deemed the project a success, and that it met the initial requirements and expectations. The aim also focused on determining whether this system can improve patient agency. This was evaluated through user testing with a non-patient cohort, demonstrating that the website is easy to use and facilitates independence in finding CTs. The extent to which this can be generalised to patients within SBUHB is uncertain, which facilitates future work. However, within the scope of this project, the aim was met.

All five objectives were met, facilitating the aim of this research. Notably, requirements discussion, design, and development (objectives 2, 3 and 4) were conducted simultaneously despite being planned as distinct stages. Each point below aligns with its initial objective:

1. Firstly, a literature review was conducted. This provided clinical context to the project and provided critical insight into barriers to CT participation and methods of alleviating them.

2. Secondly, the requirements were determined with a Urological surgeon, representing the Morriston Hospital Urology department. Requirements continuously changed throughout development, more so than initially expected in the objective. Despite this, the final list of requirements was met.

3. User interfaces were designed in collaboration with the Urological surgeon. There was a high degree of flexibility in the interface design. Similarly, a database schema was successfully designed and incorporated into the application. The overall layout and design of the site was incrementally approved by the stakeholders.

4. The application was developed successfully with ongoing clinician feedback. Although requirements changed throughout development, the final version of the site was deemed to meet these requirements which were built up over time. Additional requirements were implemented beyond the initial scope, however, these did not relate to the hypothesis.

5. Finally, the site was evaluated in relation to the hypothesis. Evaluation consisted of user testing with a non-patient group of 33 participants, supported by unstructured interviews and demonstrations with clinicians and PPI representatives. PPI representative involvement was not included in the objective, therefore, the objective was surpassed in this aspect. Usability testing focused on testing the hypothesis. Meanwhile, interviews were primarily relevant to the development of the site; however, they supported usability testing results.

Data gathered throughout this research indicates that the site can increase agency, tentatively supporting the hypothesis. However, the site was not evaluated by current SBUHB patients. As such, the hypothesis cannot be conclusively proved; nevertheless, the data collected suggests that should the site be evaluated by patients, a similar conclusion would be drawn, and the hypothesis may be proved.

6.3. Future Work

While this project was a success, it facilitates a range of future work. This involves both software development and data gathering.

Regarding web development, an increased emphasis should be placed on accessibility. Accessibility could be promoted through more robust markup and styling, along with including new features such as font size and colour options. This would be especially important when moving from proof of concept to deployment for the public. Additionally, the current site could be further evaluated from an accessibility perspective. This would involve testing against the WCAG 2.1, and including more participants with disabilities in the usability testing. Evaluation against this standard would outline potential issues, while user testing would provide more tangible insight. Ensuring that the site is accessible would increase result generalisability.

Additional research approaches would benefit the project. Further input from clinicians and PPI staff would increase generalisability and reliability. Further interviews would benefit the evaluation and any required modifications. Additionally, the staff portal of the site should be evaluated by user testing, similarly to the approach

taken for the patient portal. Although not critical to patient agency, the staff portal facilitates efficiency within the clinical teams responsible for trial recruitment.

Once expanded, the site could be evaluated as an expert system. This would involve comparing the outcomes of patients using the site to the decisions of medical professionals. This would aid in evaluating the hypothesis. Evaluation as an expert system would validate patient outcomes, determining whether patients achieve the correct outcome independently. This would involve expanding the site's content to include more trial information for current, operating trials relevant to patients within SBUHB Urology.

Testing the site with a patient group, as opposed to the general public, would significantly improve its evaluation. This would increase the confidence in the hypothesis evaluation, by incorporating actual users of the site into the data sample. This would further aid the development feedback, as the opinions of SBUHB patients are expected to differ from that of the public. Furthermore, to determine whether the site increases patient agency, as per the hypothesis, comparisons must be made to the current methods patients use to find trials. Data could be gathered through patient interviews or surveys, along with input from research nurses, as was discussed in the literature review. Although testing with personal devices facilitated generalisability, it sacrificed reliability. Testing with controlled devices, possibly a selection of mobile and desktop devices, would increase reliability. Furthermore, an increase to the sample size is warranted, and would further increase the confidence in meeting the hypothesis.

Should this project continue, an expansion of the literature review is warranted. This should increase breadth and depth. The impact of patient demographics could be further explored, such as patients' ethnicity. With permission and access from governments and research institutions, a review of other upcoming trials platforms would benefit the research.

This work could also be applied to increasing patient agency through other means, such as appointment and medicine management; however, these areas are already provided for. Furthermore, the application is currently only aimed at Urology patients within SBUHB. Immediate future work would involve increasing the scope of

the target audience by catering to other medical specialties or other hospitals. The premise of this work could be developed into a subscription model.

6.4. Conclusion

This research project has been successful. The developed site meets clinicians' requirements, and was used to generate research data and test the hypothesis.

The literature review and website development ran concurrently, influencing each other. The literature review focused on barriers to medical research enrolment, and methods to alleviate them. Development was undertaken with regular input from the stakeholders, facilitating flexibility, and resembling Scrum and FDD. The site was demonstrated to Urology clinicians within the targeted hospital, and to PPI representatives. The primary data source was usability testing involving 33 participants. This consisted of an interview, providing instructions for participants to undertake, followed by a survey to evaluate their experience. Ideally, the site would have been evaluated by current Urology patients, but this has been delegated to future work.

Research data supported findings of the literature review, particularly regarding the impact of technical literacy and age on participants searching for trials. The usability data was generally as expected. The site was well-received, with a range of responses and reactions, and an overall implication that it facilitated agency. However, SUS scores were more varied than expected.

The data confirms that the site facilitates participants independently searching for CTs. Furthermore, the data suggests that the site does not require a high level of technical literacy, and that it can be learned quickly. Almost all participants achieved the expected results of using the site, supporting the hypothesis. Given the small sample size, and limited scope of this research, the hypothesis can be endorsed, but not conclusively proved. This would require comparing patients' attitudes towards current CT search methods with those towards using the developed CT search site, facilitating comparing prior agency to that enabled by the website. Current data

cautiously supports the hypothesis, demonstrating that the site facilitates agency in non-patients from the local area.

In hindsight, requirements discussion should have been more explicit throughout development, to alleviate confusion with the customer. Furthermore, more rigidly adopting software development methodologies would have benefitted this work. Data gathering should have been considered earlier in the project, which would simplify the later parts of the dissertation. The project would also ideally have more patient involvement during early stages, to better inform development.

This section has evaluated the project against its aim, objectives, and hypothesis, described potential future work, and concluded the research. The following section reflects on the project.

7. Reflection

For this dissertation, I developed a website to help improve agency in patients within Morriston Hospital's Urology department. The site was aimed at those currently looking to join a clinical trial. The development was mostly simple as expected. This was my first experience working with a customer – a Urology surgeon leading the project, which I found difficult to adapt to. This academic endeavour was based on a paid student project. The commercial element primarily involved the development of a website against clinician requirements. For the dissertation, the site was modified to suit a hypothesis, which was evaluated through usability testing with non-patient participants. The dissertation involved writing a thorough literature review, describing my methodology and the finished website, and discussing results in relation to the hypothesis and evaluation. The project succeeded, and is now tentatively awaiting a second stage.

When I was offered this project, I was very excited to be working with a hospital, and honoured to have been chosen. I was also very intimidated, as I had not previously worked for a customer. When I started meeting with stakeholders, I felt overwhelmed, but that feeling quickly subsided once we had established a meeting routine. The project was close to me personally, which gave me more drive to complete the work to a high standard. At times, myself and the customer were not understanding each other's thought processes regarding requirements. This was extremely frustrating, likely a mutual feeling, especially because I knew it wasn't their fault. It was, however, very rewarding to work out requirements and finally come to a mutual understanding. Completing the development was very satisfying, because I saw a customer who was very happy with the product I had created over several months. It was also very rewarding to apply the skills gained throughout my studies to a real-world scenario. When beginning my research proposal, the feeling of intimidation returned, as I was struggling to comprehend exactly how to go about the project. When I became familiar with what was expected and how to achieve it, I felt confident, as the development was already mostly completed. Towards the end of the academic work, data gathering and evaluation were very rewarding, because it was an indicator that the site had also been successful from a research perspective. In hindsight, the mixed emotions were worthwhile, as this work has helped me grow as a person.

I believe the deliverables from this project are of a high quality. Some parts were not time-efficient, because of my limitations. An example of this was the literature review, which took far longer to write than anticipated. The development section was significantly delayed due to sudden, unexpected health issues on my part. When I returned, I had a fresh perspective on the work I had already completed, which improved the remaining work I completed.

I expect that the reason my development work succeeded was because the customer was very understanding and patient. I also had expert support from academics within my university, including my supervisor. The dissertation generally went well because I had already made progress on the development, and already had the contextual information I needed to conduct the literature review. Data gathering was difficult because I was uncertain of what data was needed to test the hypothesis, and many prospective participants were understandably unable or unwilling to participate. My supervisor advised me and helped me make sense of this issue.

When I next work with a customer, I will endeavour to unambiguously discuss requirements, alleviating misunderstandings. I will provide smaller, more frequent updates on development work, as to not waste our time. If I were to undertake another dissertation, I would further consider data implications earlier in the project, to simplify the whole project. I would benefit from undertaking more tasks simultaneously, whereas during this research, much of the process was linear. However, I acknowledge that some aspects must be completed this way.

Throughout this work, I have learned what exactly is involved in developing for a customer, and the ways this is different to developing for assessments. I learned a lot of new subject-specific skills, but more importantly, I developed my way of approaching projects like this. I have learned the importance of planning in advance, and improved my time management skills through this work. The project would have been simpler had I have made sure everyone had a mutual understanding before continuing.

References

[1] M. Brøgger-Mikkelsen, Z. Ali, J. R. Zibert, A. D. Andersen, and S. F. Thomsen, “Online Patient Recruitment in Clinical Trials: Systematic Review and Meta-Analysis.,” *J Med Internet Res*, vol. 22, no. 11, p. e22179, Nov. 2020, doi: 10.2196/22179.

[2] B. G. O. Sully, S. A. Julious, and J. Nicholl, “A reinvestigation of recruitment to randomised, controlled, multicenter trials: a review of trials funded by two UK funding agencies,” *Trials*, vol. 14, no. 1, p. 166, 2013, doi: 10.1186/1745-6215-14-166.

[3] S. J. Walters *et al.*, “Recruitment and retention of participants in randomised controlled trials: a review of trials funded and published by the United Kingdom Health Technology Assessment Programme,” *BMJ Open*, vol. 7, no. 3, 2017, doi: 10.1136/bmjopen-2016-015276.

[4] J. Pung and O. Rienhoff, “Key components and IT assistance of participant management in clinical research: a scoping review.,” *JAMIA Open*, vol. 3, no. 3, pp. 449–458, Oct. 2020, doi: 10.1093/jamiaopen/ooaa041.

[5] C. Zahren *et al.*, “Clinical trials site recruitment optimisation: Guidance from Clinical Trials: Impact and Quality,” *Clinical Trials*, vol. 18, no. 5, pp. 594–605, 2021, doi: 10.1177/17407745211015924.

[6] A. Rogers, N. Castree, and R. Kitchin, “human agency.” Oxford University Press, 2013. doi: 10.1093/acref/9780199599868.013.0847.

[7] D. Gregory, R. Johnston, G. Pratt, M. Watts, and S. Whatmore, *The Dictionary of Human Geography (5th edition)*, no. 5. Emerald Group Publishing Limited, 2010. doi: 10.1108/09504121011057996.

[8] O. S. Lian, S. Nettleton, H. Grange, and C. Dowrick, “‘I’m not the doctor; I’m just the patient’: Patient agency and shared decision-making in naturally occurring primary care consultations,” *Patient Educ Couns*, 2021, doi: https://doi.org/10.1016/j.pec.2021.10.031.

[9] E. J. Mills *et al.*, “Barriers to participation in clinical trials of cancer: a meta-analysis and systematic review of patient-reported factors.,” *Lancet Oncol*, vol. 7, no. 2, pp. 141–148, Feb. 2006, doi: 10.1016/S1470-2045(06)70576-9.

[10] A. R. Wong *et al.*, “Barriers to Participation in Therapeutic Clinical Trials as Perceived by Community Oncologists.,” *JCO Oncol Pract*, vol. 16, no. 9, pp. e849–e858, Sep. 2020, doi: 10.1200/JOP.19.00662.

[11] M. Agrawal, C. Grady, D. L. Fairclough, N. J. Meropol, K. Maynard, and E. J. Emanuel, “Patients’ decision-making process regarding participation in phase I oncology research.,” *J Clin Oncol*, vol. 24, no. 27, pp. 4479–4484, Sep. 2006, doi: 10.1200/JCO.2006.06.0269.

[12] N. L. Atkinson, S. L. Saperstein, H. A. Massett, C. R. Leonard, L. Grama, and R. Manrow, “Using the Internet to search for cancer clinical trials: a comparative audit of clinical trial search tools.,” *Contemp Clin Trials*, vol. 29, no. 4, pp. 555–564, Jul. 2008, doi: 10.1016/j.cct.2008.01.007.

[13] S. Stergiopoulos, K. A. Getz, and C. Blazynski, “Evaluating the Completeness of ClinicalTrials.gov.,” *Ther Innov Regul Sci*, vol. 53, no. 3, pp. 307–317, May 2019, doi: 10.1177/2168479018782885.

[14] Z. D. Goff, R. E. Heidel, K. Grabeel, and P. J. Hauptman, “Roadblocks For Patients with Heart Failure Navigating Clinicaltrials.gov,” *J Card Fail*, vol. 26, no. 10, Supplement, pp. S126–S127, 2020, doi: https://doi.org/10.1016/j.cardfail.2020.09.365.

[15] J. L. Ridgeway, G. B. Asiedu, K. Carroll, M. Tenney, A. Jatoi, and C. Radecki Breitkopf, “Patient and family member perspectives on searching for cancer clinical trials: A qualitative interview study.,” *Patient Educ Couns*, vol. 100, no. 2, pp. 349–354, Feb. 2017, doi: 10.1016/j.pec.2016.08.020.

[16] E. Isaksson, P. Wester, A. C. Laska, P. Näsman, and E. Lundström, “Identifying important barriers to recruitment of patients in randomised clinical studies using a questionnaire for study personnel,” *Trials*, vol. 20, no. 1, p. 618, 2019, doi: 10.1186/s13063-019-3737-1.

[17] J. E. Stryker, R. J. Wray, K. M. Emmons, E. Winer, and G. Demetri, “Understanding the decisions of cancer clinical trial participants to enter

research studies: factors associated with informed consent, patient satisfaction, and decisional regret.," *Patient Educ Couns*, vol. 63, no. 1–2, pp. 104–109, Oct. 2006, doi: 10.1016/j.pec.2005.09.006.

[18] K. Cox, "Informed consent and decision-making: patients' experiences of the process of recruitment to phases I and II anti-cancer drug trials.," *Patient Educ Couns*, vol. 46, no. 1, pp. 31–38, Jan. 2002, doi: 10.1016/s0738-3991(01)00147-1.

[19] A. Anderson, D. Borfitz, and K. Getz, "Global Public Attitudes About Clinical Research and Patient Experiences With Clinical Trials," *JAMA Netw Open*, vol. 1, no. 6, pp. e182969–e182969, 2018, doi: 10.1001/jamanetworkopen.2018.2969.

[20] M. S. Sedrak *et al.*, "Older adult participation in cancer clinical trials: A systematic review of barriers and interventions.," *CA Cancer J Clin*, vol. 71, no. 1, pp. 78–92, Jan. 2021, doi: 10.3322/caac.21638.

[21] B. Friend *et al.*, "Clinical trial enrollment of adolescent and young adult patients with cancer: a systematic review of the literature and proposed solutions," *Clin Oncol Adolesc Young Adults*, vol. Volume 6, pp. 51–59, Feb. 2017, doi: 10.2147/COAYA.S70375.

[22] C. Simon and S. Hegedus, "Exploring websites on cancer clinical trials: an empirical review.," *Contemp Clin Trials*, vol. 26, no. 5, pp. 530–533, Oct. 2005, doi: 10.1016/j.cct.2005.07.004.

[23] Datamonitor PLC, "Clinical Trial Recruitment Websites Case Study: Key Players in Online Patient Recruitment," 2008. [Online]. Available: https://ezproxy.uwtsd.ac.uk/login?url=https://search.ebscohost.com/login.aspx?direct=true&db=bth&AN=36349366&site=ehost-live

[24] V. Monaco and S. K. Krills, "On-line information about cancer clinical trials: evaluating the Web sites of comprehensive cancer centers.," *AMIA Annu Symp Proc*, vol. 2003, pp. 470–474, 2003.

[25] E. Rodríguez-Torres, M. M. González-Pérez, and C. Díaz-Pérez, "Barriers and facilitators to the participation of subjects in clinical trials: An overview of

reviews.," *Contemp Clin Trials Commun*, vol. 23, p. 100829, Sep. 2021, doi: 10.1016/j.conctc.2021.100829.

[26] T. Buttgereit *et al.*, "Barriers and potential solutions in the recruitment and retention of older patients in clinical trials-lessons learned from six large multicentre randomized controlled trials.," *Age Ageing*, vol. 50, no. 6, pp. 1988–1996, Nov. 2021, doi: 10.1093/ageing/afab147.

[27] M. Tang *et al.*, "Are clinical trial eligibility criteria representative of older patients with lung cancer? A population-based data linkage study.," *J Geriatr Oncol*, vol. 12, no. 6, pp. 930–936, Jul. 2021, doi: 10.1016/j.jgo.2021.02.003.

[28] T. Godskesen, "Patients in Clinical Cancer Trials : Understanding, Motivation and Hope," PhD thesis, Uppsala University, 2015.

[29] M. S. Sedrak *et al.*, "Barriers to clinical trial enrollment of older adults with cancer: A qualitative study of the perceptions of community and academic oncologists," *J Geriatr Oncol*, vol. 11, no. 2, pp. 327–334, 2020, doi: https://doi.org/10.1016/j.jgo.2019.07.017.

[30] J. M. Unger, E. Cook, E. Tai, and A. Bleyer, "The Role of Clinical Trial Participation in Cancer Research: Barriers, Evidence, and Strategies," *American Society of Clinical Oncology Educational Book*, no. 36, pp. 185–198, May 2016, doi: 10.1200/EDBK_156686.

[31] M. S. Sedrak *et al.*, "Barriers to clinical trial enrollment of older adults with cancer: A systematic review.," *Journal of Clinical Oncology*, vol. 37, no. 15_suppl, pp. e18130–e18130, May 2019, doi: 10.1200/JCO.2019.37.15_suppl.e18130.

[32] P. Fearn, A. Avenell, S. McCann, A. C. Milne, and G. Maclennan, "Factors influencing the participation of older people in clinical trials - data analysis from the MAVIS trial.," *J Nutr Health Aging*, vol. 14, no. 1, pp. 51–56, Jan. 2010, doi: 10.1007/s12603-010-0009-x.

[33] J. Liu *et al.*, "Strategies to Improve Participation of Older Adults in Cancer Research.," *J Clin Med*, vol. 9, no. 5, May 2020, doi: 10.3390/jcm9051571.

[34] E. J. Siembida *et al.*, “Systematic review of barriers and facilitators to clinical trial enrollment among adolescents and young adults with cancer: Identifying opportunities for intervention,” *Cancer*, vol. 126, no. 5, pp. 949–957, Mar. 2020, doi: 10.1002/cncr.32675.

[35] S. J. Nass *et al.*, “Identifying and addressing the needs of adolescents and young adults with cancer: summary of an Institute of Medicine workshop.,” *Oncologist*, vol. 20, no. 2, pp. 186–195, Feb. 2015, doi: 10.1634/theoncologist.2014-0265.

[36] National Cancer Institute, “Adolescents and Young Adults (AYAs) with Cancer - NCI,” 2020. https://www.cancer.gov/types/aya (accessed Jul. 12, 2022).

[37] J. A. Ellis *et al.*, “Systems-Level Change to Alleviate Barriers to Cancer Clinical Trial Access for Adolescents and Young Adults in Australia.,” *J Adolesc Young Adult Oncol*, vol. 11, no. 2, pp. 173–180, Apr. 2022, doi: 10.1089/jayao.2021.0026.

[38] A. Bleyer, E. Tai, and S. Siegel, “Role of clinical trials in survival progress of American adolescents and young adults with cancer-and lack thereof.,” *Pediatr Blood Cancer*, vol. 65, no. 8, p. e27074, Aug. 2018, doi: 10.1002/pbc.27074.

[39] M. E. Roth *et al.*, “Low Enrollment of Adolescents and Young Adults Onto Cancer Trials: Insights From the Community Clinical Oncology Program.,” *J Oncol Pract*, vol. 12, no. 4, pp. e388-95, Apr. 2016, doi: 10.1200/JOP.2015.009084.

[40] T. de Rojas *et al.*, “Access to Clinical Trials for Adolescents and Young Adults With Cancer: A Meta-Research Analysis.,” *JNCI Cancer Spectr*, vol. 3, no. 4, p. pkz057, Dec. 2019, doi: 10.1093/jncics/pkz057.

[41] Z. Zolkipli-Cunningham *et al.*, “Mitochondrial disease patient motivations and barriers to participate in clinical trials.,” *PLoS One*, vol. 13, no. 5, p. e0197513, 2018, doi: 10.1371/journal.pone.0197513.

[42] M. Lee *et al.*, “Factors influencing clinical trial participation for adult and pediatric patients with cystic fibrosis.,” *J Cyst Fibros*, vol. 20, no. 1, pp. 57–60, Jan. 2021, doi: 10.1016/j.jcf.2020.08.019.

[43] R. Brierley, D. Holmes, A. Ceschia, and J. Jouret, “Teenage Cancer Trust: pursuing equality.,” *Lancet Oncol*, vol. 10, no. 5, pp. 455–458, May 2009, doi: 10.1016/s1470-2045(09)70135-4.

[44] Teenage Cancer Trust, “Our cancer units and wards | Teenage Cancer Trust,” *2022*. https://www.teenagecancertrust.org/help-and-support/our-cancer-units (accessed Jul. 12, 2022).

[45] S. Misra, “Randomized double blind placebo control studies, the ‘Gold Standard’ in intervention based studies.,” *Indian J Sex Transm Dis AIDS*, vol. 33, no. 2, pp. 131–134, Jul. 2012, doi: 10.4103/0253-7184.102130.

[46] V. Forcina *et al.*, “Perceptions and attitudes toward clinical trials in adolescent and young adults with cancer: a systematic review.,” *Adolesc Health Med Ther*, vol. 9, pp. 87–94, 2018, doi: 10.2147/AHMT.S163121.

[47] S. C. WESTEN *et al.*, “805-P: Barriers and Facilitators of Participation in Clinical Trials among Youth and Young Adults with Type 1 Diabetes and Their Caregivers,” *Diabetes*, vol. 68, no. Supplement_1, 2019, doi: 10.2337/db19-805-P.

[48] L. Hanna, S. D. Gill, L. Newstead, M. Hawkins, and R. H. Osborne, “Patient perspectives on a personally controlled electronic health record used in regional Australia.,” *Health Inf Manag*, vol. 46, no. 1, pp. 42–48, Jan. 2017, doi: 10.1177/1833358316661063.

[49] B. Hoogenbosch, J. Postma, J. M. de Man-van Ginkel, N. A. Tiemessen, J. J. van Delden, and H. van Os-Medendorp, “Use and the Users of a Patient Portal: Cross-Sectional Study.,” *J Med Internet Res*, vol. 20, no. 9, p. e262, Sep. 2018, doi: 10.2196/jmir.9418.

[50] V. Ramon *et al.*, “SEAMPAT,” in *Computers Helping People with Special Needs*, 2016, pp. 269–276.

[51] S. Marien *et al.*, “A User-Centered design and usability testing of a web-based medication reconciliation application integrated in an eHealth network,” *Int J Med Inform*, vol. 126, pp. 138–146, 2019, doi: https://doi.org/10.1016/j.ijmedinf.2019.03.013.

[52] A. A. Sardaneh, R. Burke, A. Ritchie, A. J. McLachlan, and E. C. Lehnbom, “Pharmacist-led admission medication reconciliation before and after the implementation of an electronic medication management system,” *Int J Med Inform*, vol. 101, pp. 41–49, 2017, doi: https://doi.org/10.1016/j.ijmedinf.2017.02.001.

[53] B. Qudah and K. Luetsch, “The influence of mobile health applications on patient - healthcare provider relationships: A systematic, narrative review,” *Patient Educ Couns*, vol. 102, no. 6, pp. 1080–1089, 2019, doi: https://doi.org/10.1016/j.pec.2019.01.021.

[54] J. M. Metz, C. Coyle, C. Hudson, and M. Hampshire, “An Internet-based cancer clinical trials matching resource.,” *J Med Internet Res*, vol. 7, no. 3, p. e24, Jul. 2005, doi: 10.2196/jmir.7.3.e24.

[55] R. Mohs *et al.*, “Novel recruitment strategies for clinical trials: a preliminary report from the global alzheimer’s platform network (GAP-NET),” *Alzheimer’s & Dementia*, vol. 13, no. 7S Part 30, pp. 1454–1455, 2017, doi: https://doi.org/10.1016/j.jalz.2017.07.511.

[56] Y. Fenner *et al.*, “Web-based recruiting for health research using a social networking site: an exploratory study.,” *J Med Internet Res*, vol. 14, no. 1, p. e20, Feb. 2012, doi: 10.2196/jmir.1978.

[57] D. Toddenroth, J. Sivagnanasundaram, H.-U. Prokosch, and T. Ganslandt, “Concept and implementation of a study dashboard module for a continuous monitoring of trial recruitment and documentation.,” *J Biomed Inform*, vol. 64, pp. 222–231, Dec. 2016, doi: 10.1016/j.jbi.2016.10.010.

[58] W. A. Mattingly *et al.*, “Real-Time Enrollment Dashboard For Multisite Clinical Trials.,” *Contemp Clin Trials Commun*, vol. 1, pp. 17–21, Oct. 2015, doi: 10.1016/j.conctc.2015.09.001.

[59] E. Cohen *et al.*, “Adoption, acceptability, and accuracy of an online clinical trial matching website for breast cancer.,” *J Med Internet Res*, vol. 14, no. 4, p. e97, Jul. 2012, doi: 10.2196/jmir.1855.

[60] N. L. Atkinson, H. A. Massett, C. Mylks, B. Hanna, M. J. Deering, and B. W. Hesse, “User-centered research on breast cancer patient needs and

preferences of an Internet-based clinical trial matching system.," *J Med Internet Res*, vol. 9, no. 2, p. e13, May 2007, doi: 10.2196/jmir.9.2.e13.

[61] C. Sanchez *et al.*, "Social media recruitment for mental health research: A systematic review.," *Compr Psychiatry*, vol. 103, p. 152197, Nov. 2020, doi: 10.1016/j.comppsych.2020.152197.

[62] S. Crawford *et al.*, "'It's not black and white': Public health researchers' and ethics committees' perceptions of engaging research participants online," *Internet Research*, vol. 29, no. 1, pp. 123–143, Jan. 2019, doi: 10.1108/IntR-07-2017-0278.

[63] M. A. Moreno, N. Goniu, P. S. Moreno, and D. Diekema, "Ethics of social media research: common concerns and practical considerations.," *Cyberpsychol Behav Soc Netw*, vol. 16, no. 9, pp. 708–713, Sep. 2013, doi: 10.1089/cyber.2012.0334.

[64] E. Bragard, C. B. Fisher, and B. L. Curtis, "'They know what they are getting into:' Researchers confront the benefits and challenges of online recruitment for HIV research.," *Ethics Behav*, vol. 30, no. 7, pp. 481–495, 2020, doi: 10.1080/10508422.2019.1692663.

[65] C. Whitaker, S. Stevelink, and N. Fear, "The Use of Facebook in Recruiting Participants for Health Research Purposes: A Systematic Review.," *J Med Internet Res*, vol. 19, no. 8, p. e290, Aug. 2017, doi: 10.2196/jmir.7071.

[66] D. E. Ramo, T. M. S. Rodriguez, K. Chavez, M. J. Sommer, and J. J. Prochaska, "Facebook Recruitment of Young Adult Smokers for a Cessation Trial: Methods, Metrics, and Lessons Learned.," *Internet Interv*, vol. 1, no. 2, pp. 58–64, Apr. 2014, doi: 10.1016/j.invent.2014.05.001.

[67] L. Thornton, P. J. Batterham, D. B. Fassnacht, F. Kay-Lambkin, A. L. Calear, and S. Hunt, "Recruiting for health, medical or psychosocial research using Facebook: Systematic review," *Internet Interv*, vol. 4, pp. 72–81, 2016, doi: https://doi.org/10.1016/j.invent.2016.02.001.

[68] M. S. Sedrak *et al.*, "Physician Perceptions of the Use of Social Media for Recruitment of Patients in Cancer Clinical Trials.," *JAMA Netw Open*, vol. 2, no. 9, p. e1911528, Sep. 2019, doi: 10.1001/jamanetworkopen.2019.11528.

[69] L. Akers and J. S. Gordon, “Using Facebook for Large-Scale Online Randomized Clinical Trial Recruitment: Effective Advertising Strategies.,” *J Med Internet Res*, vol. 20, no. 11, p. e290, Nov. 2018, doi: 10.2196/jmir.9372.

[70] M. Zlotorzynska, J. A. Bauermeister, J. M. Golinkoff, W. Lin, T. H. Sanchez, and L. Hightow-Weidman, “Online recruitment of youth for mHealth studies.,” *Mhealth*, vol. 7, p. 27, 2021, doi: 10.21037/mhealth-20-64.

[71] J. N. Parker, A. S. Hunter, J. A. Bauermeister, E. E. Bonar, A. Carrico, and R. Stephenson, “Comparing Social Media and In-Person Recruitment: Lessons Learned From Recruiting Substance-Using, Sexual and Gender Minority Adolescents and Young Adults for a Randomized Control Trial.,” *JMIR Public Health Surveill*, vol. 7, no. 12, p. e31657, Dec. 2021, doi: 10.2196/31657.

[72] A. O’Connor, L. Jackson, L. Goldsmith, and H. Skirton, “Can I get a retweet please? Health research recruitment and the Twittersphere.,” *J Adv Nurs*, vol. 70, no. 3, pp. 599–609, Mar. 2014, doi: 10.1111/jan.12222.

[73] C. N. Bisset, B. Carter, J. Law, J. Hewitt, K. Parmar, and S. J. Moug, “The influence of social media on recruitment to surgical trials.,” *BMC Med Res Methodol*, vol. 20, no. 1, p. 201, Jul. 2020, doi: 10.1186/s12874-020-01072-1.

[74] M. Abuhmida and K. Jones, “Research Methods II.” PowerPoint presentation, University of Wales Trinity Saint David, 2019.

[75] D. Crowther , Lancaster, Geoffrey,, “Research methods : a concise introduction to research in management and business consultancy.” Elsevier, Oxford, 2008.

[76] M. van Manen and C. A. Adams, “Phenomenology,” in *International Encyclopedia of Education (Third Edition)*, Third Edit., P. Peterson, E. Baker, and B. McGaw, Eds. Oxford: Elsevier, 2010, pp. 449–455. doi: https://doi.org/10.1016/B978-0-08-044894-7.01539-6.

[77] M. Heyvaert, B. Maes, and P. Onghena, “Mixed methods research synthesis: definition, framework, and potential,” *Qual Quant*, vol. 47, no. 2, pp. 659–676, Feb. 2013, doi: 10.1007/s11135-011-9538-6.

[78] R. B. Johnson, A. J. Onwuegbuzie, and L. A. Turner, “Toward a Definition of Mixed Methods Research,” *J Mix Methods Res*, vol. 1, no. 2, pp. 112–133, Apr. 2007, doi: 10.1177/1558689806298224.

[79] U.S. Department of Health & Human Services, “User Experience Basics | Usability.gov,” 2020. https://www.usability.gov/what-and-why/user-experience.html# (accessed Feb. 19, 2020).

[80] O. Sohaib, W. Hussain, and M. K. Badini, “User Experience (UX) and the Web Accessibility Standards,” vol. 8, no. 3, pp. 584–588, 2011.

[81] N. McNamara and J. Kirakowski, “Functionality, Usability, and User Experience: Three Areas of Concern,” *Interactions*, vol. 13, no. 6, pp. 26–28, Nov. 2006, doi: 10.1145/1167948.1167972.

[82] Shawn Lawton Henry, “Introduction to Web Accessibility | Web Accessibility Initiative (WAI) | W3C,” 2019. https://www.w3.org/WAI/fundamentals/accessibility-intro/#what (accessed Feb. 20, 2020).

[83] W3C, “Web Content Accessibility Guidelines (WCAG) 2.1,” 2018. https://www.w3.org/TR/WCAG21/ (accessed Jul. 29, 2022).

[84] W3C, “Press Release: W3C Launches International Program Office for WAI,” 1997. https://www.w3.org/Press/IPO-announce (accessed Aug. 09, 2022).

[85] D. K. Raynor, P. Knapp, J. Silcock, B. Parkinson, and K. Feeney, “‘User-testing’ as a method for testing the fitness-for-purpose of written medicine information,” *Patient Educ Couns*, vol. 83, no. 3, pp. 404–410, 2011, doi: https://doi.org/10.1016/j.pec.2011.03.016.

[86] P. Knapp, D. K. Raynor, J. Silcock, and B. Parkinson, “Can user testing of a clinical trial patient information sheet make it fit-for-purpose?--a randomized controlled trial.,” *BMC Med*, vol. 9, p. 89, Jul. 2011, doi: 10.1186/1741-7015-9-89.

[87] R. Sheridan *et al.*, “User testing digital, multimedia information to inform children, adolescents and their parents about healthcare trials,” *Journal of Child Health Care*, vol. 23, no. 3, pp. 468–482, 2019, doi: 10.1177/1367493518807325.

[88] C. Putnam, M. Puthenmadom, M. A. Cuerdo, W. Wang, and N. Paul, “Adaptation of the System Usability Scale for User Testing with Children,” in *Extended Abstracts of the 2020 CHI Conference on Human Factors in Computing Systems*, 2020, pp. 1–7. doi: 10.1145/3334480.3382840.

[89] J. Brooke, “SUS-A quick and dirty usability scale,” 1996.

[90] U.S. Department of Health & Human Services, “System Usability Scale (SUS) | Usability.gov.” https://www.usability.gov/how-to-and-tools/methods/system-usability-scale.html (accessed Feb. 20, 2020).

[91] J. Brooke, “SUS: A Retrospective,” *J. Usability Studies*, vol. 8, no. 2, pp. 29–40, Feb. 2013.

[92] P. Kortum and S. C. Peres, “The Relationship Between System Effectiveness and Subjective Usability Scores Using the System Usability Scale,” *Int J Hum Comput Interact*, vol. 30, no. 7, pp. 575–584, 2014, doi: 10.1080/10447318.2014.904177.

[93] MDN contributors, “Navigator.userAgent - Web APIs | MDN,” 2022. https://developer.mozilla.org/en-US/docs/Web/API/Navigator/userAgent (accessed Jul. 26, 2022).

[94] P. Gill, K. Stewart, E. Treasure, and B. Chadwick, “Methods of data collection in qualitative research: interviews and focus groups,” *Br Dent J*, vol. 204, no. 6, pp. 291–295, 2008, doi: 10.1038/bdj.2008.192.

[95] Scrum.org, “What is Scrum?,” 2022. https://www.scrum.org/resources/what-is-scrum (accessed Apr. 08, 2022).

[96] T. Pagotto, J. A. Fabri, A. Lerario, and J. A. Gonçalves, “Scrum solo: Software process for individual development,” in *2016 11th Iberian Conference on Information Systems and Technologies (CISTI)*, 2016, pp. 1–6. doi: 10.1109/CISTI.2016.7521555.

[97] A. S. Patrucco, F. Canterino, and I. Minelgaite, “How do Scrum Methodologies Influence the Team’s Cultural Values? A Multiple Case Study on Agile Teams in Nonsoftware Industries,” *IEEE Trans Eng Manag*, pp. 1–11, 2022, doi: 10.1109/TEM.2022.3146717.

[98] J. Sutherland, C. R. Jakobsen, and K. Johnson, “Scrum and CMMI Level 5: The Magic Potion for Code Warriors,” in *Proceedings of the 41st Annual Hawaii International Conference on System Sciences (HICSS 2008)*, 2008, p. 466. doi: 10.1109/HICSS.2008.384.

[99] M. Al-Zewairi, M. Biltawi, W. Etaiwi, and A. Shaout, “Agile Software Development Methodologies: Survey of Surveys,” *Journal of Computer and Communications*, vol. 05, pp. 74–97, 2017, doi: 10.4236/jcc.2017.55007.

[100] A. Ahmed, S. Ahmad, N. Ehsan, E. Mirza, and S. Z. Sarwar, “Agile software development: Impact on productivity and quality,” in *2010 IEEE International Conference on Management of Innovation Technology*, 2010, pp. 287–291. doi: 10.1109/ICMIT.2010.5492703.

[101] G. Kumar and P. Bhatia, “Impact of Agile Methodology on Software Development Process,” *International Journal of Computer Technology and Electronics Engineering (IJCTEE)*, vol. 2, pp. 2249–6343, 2012.

[102] A. F. Chowdhury and M. N. Huda, “Comparison between Adaptive Software Development and Feature Driven Development,” in *Proceedings of 2011 International Conference on Computer Science and Network Technology*, 2011, vol. 1, pp. 363–367. doi: 10.1109/ICCSNT.2011.6181977.

[103] S. Ahmed, “Evaluation for Feature Driven Development Paradigm in Context of Architecture Design Augmentation and Perspective Implications,” *International Journal of Advanced Computer Science and Applications*, vol. 9, 2018, doi: 10.14569/IJACSA.2018.090334.

[104] The jQuery Foundation, “jQuery, v4.4.0.” 2020. Accessed: Mar. 08, 2020. [Online]. Available: https://github.com/jquery/jquery

[105] Bootstrap, “Bootstrap · The most popular HTML, CSS, and JS library in the world.,” 2018. https://getbootstrap.com/ (accessed Jan. 07, 2019).

[106] Bootstrap, “Accessibility · Bootstrap.” https://getbootstrap.com/docs/4.0/getting-started/accessibility/ (accessed Aug. 04, 2022).

[107] Fonticons Inc., “Font Awesome,” 2022. https://fontawesome.com/ (accessed Jul. 29, 2022).

[108] B. R. Matzelle, M. Bointon, A. Prevost, and J. Jagielski, “PHPMailer/PHPMailer: The classic email sending library for PHP,” 2022. https://github.com/PHPMailer/PHPMailer (accessed Jul. 29, 2022).

[109] World Wide Web Consortium, “The W3C Markup Validation Service,” 2013. https://validator.w3.org/ (accessed Jul. 29, 2022).

[110] World Wide Web Consortium, “The W3C CSS Validation Service,” 2009. https://jigsaw.w3.org/css-validator/ (accessed Jul. 29, 2022).

[111] A. Sitnik, “Autoprefixer CSS online,” 2017. https://autoprefixer.github.io/ (accessed Jul. 29, 2022).

[112] Deque Systems Inc., “dequelabs/axe-core: Accessibility engine for automated Web UI testing,” 2022. https://github.com/dequelabs/axe-core (accessed Jul. 29, 2022).

[113] BrowserStack, “Most Reliable App & Cross Browser Testing Platform | BrowserStack,” 2022. https://www.browserstack.com/ (accessed Aug. 06, 2022).

[114] Information Comissioner’s Office, “Guidance on the rules on use of cookies and similar technologies,” 2012. [Online]. Available: https://ico.org.uk/media/for-organisations/documents/1545/cookies_guidance.pdf

[115] Information Comissioner’s Office, “Guide to the Privacy and Electronic Communications Regulations,” 2018.

[116] Office for National Statistics, “Exploring the UK’s digital divide - Office for National Statistics,” 2019. [Online]. Available: https://www.ons.gov.uk/peoplepopulationandcommunity/householdcharacteristics/homeinternetandsocialmediausage/articles/exploringtheuksdigitaldivide/2019-03-04#:~:text=It estimates that the number,the five basic digital skills).

[117] Lexico.com, “CUMBERSOME | Meaning & Definition for UK English | Lexico.com,” 2022. https://www.lexico.com/definition/cumbersome (accessed Aug. 18, 2022).

[118] A. Bangor, P. T. Kortum, and J. T. Miller, “An Empirical Evaluation of the System Usability Scale,” *Int J Hum Comput Interact*, vol. 24, no. 6, pp. 574–594, 2008, doi: 10.1080/10447310802205776.

[119] A. Bangor, P. Kortum, and J. Miller, “Determining What Individual SUS Scores Mean: Adding an Adjective Rating Scale,” *J. Usability Stud.*, vol. 4, pp. 114–123, Apr. 2009.

[120] J. Sauro, *A practical guide to the system usability scale : background, benchmarks & best practices*. Denver, Colorado, 2011.

[121] T. S. Tullis and J. N. Stetson, “A Comparison of Questionnaires for Assessing Website Usability,” 2004.

Background Reading

D. Roberts *et al*., “A national survey of the barriers and facilitators to conducting clinical trials in radiotherapy.” 2022. doi: 10.13140/RG.2.2.29338.93126.

M. J. Hall *et al*., “Barriers to participation in cancer prevention clinical trials.,” *Acta Oncol*, vol. 49, no. 6, pp. 757–766, Aug. 2010, doi: 10.3109/0284186X.2010.485209.

A. Mahmud, O. Zalay, A. Springer, K. Arts, and E. Eisenhauer, “Barriers to participation in clinical trials: a physician survey.,” *Curr Oncol*, vol. 25, no. 2, pp. 119–125, Apr. 2018, doi: 10.3747/co.25.3857.

S. Ross, A. Grant, C. Counsell, W. Gillespie, I. Russell, and R. Prescott, “Barriers to participation in randomised controlled trials: a systematic review.,” *J Clin Epidemiol*, vol. 52, no. 12, pp. 1143–1156, Dec. 1999, doi: 10.1016/s0895-4356(99)00141-9.

M. S. Sedrak, R. B. Cohen, R. M. Merchant, and M. M. Schapira, “Cancer Communication in the Social Media Age,” *JAMA Oncol*, vol. 2, no. 6, pp. 822–823, 2016, doi: 10.1001/jamaoncol.2015.5475.

A. Kearney *et al*., “Development of an online resource for recruitment research in clinical trials to organise and map current literature,” *Clinical Trials*, vol. 15, no. 6, pp. 533–542, Aug. 2018, doi: 10.1177/1740774518796156.

G. Colon-Otero *et al*., “Disparities in participation in cancer clinical trials in the United States : a symptom of a healthcare system in crisis.,” *Cancer*, vol. 112, no. 3, pp. 447–454, Feb. 2008, doi: 10.1002/cncr.23201.

R. Marks, H. Bristol, M. Conlon, and C. J. Pepine, “Enhancing clinical trials on the internet: Lessons from INVEST,” *Clin Cardiol*, vol. 24, no. S5, pp. V-17-V–23, 2001, doi: https://doi.org/10.1002/clc.4960241707.

R. Abu Farha, K. H. Alzoubi, O. F. Khabour, and T. L. Mukattash, “Factors Influencing Public Knowledge and Willingness to Participate in Biomedical Research in Jordan: A National Survey.,” *Patient Prefer Adherence*, vol. 14, pp. 1373–1379, 2020, doi: 10.2147/PPA.S261903.

S. K. McCann, M. K. Campbell, and V. A. Entwistle, “Reasons for participating in randomised controlled trials: conditional altruism and considerations for self.,” *Trials*, vol. 11, p. 31, Mar. 2010, doi: 10.1186/1745-6215-11-31.

A. Tate, “Treatment Recommendations in Oncology Visits: Implications for Patient Agency and Physician Authority.,” *Health Commun*, vol. 34, no. 13, pp. 1597–1607, Nov. 2019, doi: 10.1080/10410236.2018.1514683.

L. Arab, H. Hahn, J. Henry, S. Chacko, A. Winter, and M. C. Cambou, “Using the web for recruitment, screen, tracking, data management, and quality control in a dietary assessment clinical validation trial,” *Contemp Clin Trials*, vol. 31, no. 2, pp. 138–146, 2010, doi: https://doi.org/10.1016/j.cct.2009.11.005.

A. S. McAlearney, P. H. Song, and K. L. Reiter, “Why providers participate in clinical trials: considering the National Cancer Institute’s Community Clinical Oncology Program.,” *Contemp Clin Trials*, vol. 33, no. 6, pp. 1143–1149, Nov. 2012, doi: 10.1016/j.cct.2012.08.008.

Appendices

Appendix A – Usability Testing Instructions

Medical Trials Website Evaluation

CONSENT

This usability testing includes some medical topics which some participants may find upsetting. Please read the consent information on the website. To continue with this research, you'll need to confirm that you consent to participating and that you are at least 18 years of age.

Introduction

This is a usability test of a website which was developed to help patients find medical trials for their condition. **For this evaluation, you will take on the persona of the patient who is searching for trials and use a web application to do so. You will be provided with medical and contextual details for the patient you are portraying.**

Your participation is anonymous, and you may withdraw from this research at any point. On request, you may access the results of this research once it is completed.

This testing uses trial data which has been adapted from real trials, to fit this evaluation's purpose. For example, some eligibility criteria and locations may have been altered.

When evaluating the site, you are not expected to follow any links to external sites in order to complete the tasks, **with the exception of a link to a survey form.**

Please note: You are not being tested; rather, you are testing the application

This should take around 20-30 minutes.

Go to the provided address in your preferred browser.

Please read the research consent statement and if you consent, click the consent button.

What you see will be the patient home page. This is what you would see as a patient, having been referred to this website by your clinician.

This site optionally uses cookies to improve the user experience. You are recommended, but not required, to accept the optional cookies.

Testing the website: searching for trials

You will now test the website as if you were a patient. Your end goal is to find a trial which you are eligible for.

Your first activities are as follows:

1. From the home page, navigate to the trial search page.
2. Work through the trial search form using your allocated clinical details which I will provide you. **There is no need to use the optional keyword search box.**

   Once you reach the search results page, do not choose a trial – wait for further instructions.

Your allocated patient details are:

You are Mr John Doe, 43 years old.

Condition specialty:
Urology

Affected organ:
Prostate

Condition:
Localised prostate cancer

Testing the website: viewing trials

You should now see a short list of trials matching your condition details.

For this step, make sure to view each trial in a top-down fashion: view the first result first, then the second, etc.

View the first trial in the list, and check if it is suitable for you, by:

1. Checking the trial location is in the same city as in your allocated patient details. **This patient lives in Swansea, and is unable to travel outside of Swansea city to participate in medical research**
2. Checking you meet all of the trial's eligibility criteria

If a trial is not in your location, or you do not meet its eligibility criteria, return to the results list and check the next trial. Repeat this until you find an eligible trial.

Once you find a trial you are eligible for, stay on the page and wait for further instructions.

Your details:
Condition specialty:
Urology

Affected organ:
Prostate

Condition:
Localised prostate cancer

Have any other conditions?
No
Had any treatment for your condition?
Radiotherapy
Taking any medications?
No

Any allergies?
Contrast dyes

Age:
43

Biological sex:
Male

City of residence:
Swansea

Testing the website: making contact

Now that you have found a trial you are eligible for, please contact the trial's contact point using the website. Provide the below details:

(PLEASE DO NOT USE YOUR REAL DETAILS)

Title:
Mr

First name:
John

Last name:
Doe

Phone:
0123456789 *(No spaces)*

Email:
Leave blank

Please also find and note the phone number of the contact point for this trial.

Finally, please return to the home page. There, at the top of the page, you will see a link to complete a survey about your experience. This is very important as your feedback from this form helps improve this application for future patients.

Appendix B – Usability Testing Survey

N.B.: This form was converted from the web interface to PDF, and so is not entirely representative of what participants saw. The Microsoft Forms page is available at:

https://forms.office.com/Pages/ResponsePage.aspx?id=-REPTm4EBUWcuNshUjEelesW5ffZJhJNpXUY1S2qvBRUMDU3WDVBUzlVRVlWNEtTOUYxQ0RSUlBOVS4u

Medical Trials Website Evaluation

This survey is to document your experience from the website testing you have carried out, which will help future patients to find trials suitable for them.

Your participation is anonymous, and you may withdraw from this research at any point. On request, you may access the results of this research once it is completed.

About this research data:

This research is being conducted in collaboration with Swansea Bay University Health Board (SBUHB).
All data generated by this form will be kept in password protected cloud storage on the University Office 365 system. Any USB devices or computers used to store backups or transfer data will be password protected. Devices holding this research data will be reformatted at the end of the project in order to destroy the data.

In accordance with the DPA2018, you have the right to ask to see what data is held relating to your responses, and this data will be deleted immediately on your request, therefore not being used in the project.

This research data will be made available only to the following parties:

- The principal researcher
- The project supervisor
- Any second markers or external examiners, on request
- The commercial partner - Swansea Bay University Health Board
- You, on request

Contacts:

Principal researcher: Mr Austin Hooper 1700481@student.uwtsd.ac.uk
Project supervisor: Dr Tim Bashford - tim.bashford@uwtsd.ac.uk

Participation consent

Do you consent to participating in this research by completing this form and its activities? *

This usability testing includes some medical topics which some participants may find upsetting.

Please indicate that you consent to participating in this research and your anonymised responses being used.

- [ ] I consent to participating in this research activity

Please indicate that you are at least 18 years of age. *

- [ ] I am 18 years of age or older

Please provide some basic information about yourself

NOTE: Please use your real details for this, and NOT the allocated patient details. This information is collected to explore links and correlations between data.

What is your gender? *

- ◯ Female
- ◯ Male
- ◯ Non-binary / other
- ◯ Prefer not to say

Which age range do you fall within? *

- ◯ 18-24
- ◯ 25-34
- ◯ 35-44
- ◯ 45-54
- ◯ 55-64
- ◯ 65+
- ◯ Prefer not to say

Please rate your own technical ability/literacy from the options below, taking into consideration the descriptions for each category. *

- ◯ Expert: I work or study in IT
- ◯ Proficient: I use computers frequently for a range of tasks (such as work), with little difficulty
- ◯ Fair: I can use a phone/computer for basic tasks such as checking emails and browsing the web
- ◯ Infrequent user: I don't use phones or computers often

Do you consider yourself to have any disability or difficulty which may impact computer or website usage?

For example colour blindness or other visual impairments *

- ◯ Yes
- ◯ No
- ◯ Prefer not to say

Please list any relevant disabilities you have below: *

Evaluation methods

Please provide some basic information about how you accessed the website:

Which type of device did you view the website on? *

- ◯ Mobile (phone, tablet etc.)
- ◯ Desktop (laptop, PC etc.)

How did you complete this activity? *

- ◯ Via a phone / audio call
- ◯ Via a video call while sharing my screen

Website testing outcomes

Were you able to find and use the trial search form, without assistance?

NOTE: being provided/reminded your patient details is not considered "assistance". A patient using this system in a real scenario would already know their clinical details. *

- ◯ Yes
- ◯ No

Were you able to navigate trials and find a trial which you were eligible for, without assistance? *

- ◯ Yes
- ◯ No

Were you able to send your details to the trial's contact point and find their phone number, without assistance? *

- ◯ Yes
- ◯ No

Please list the phone number of the contact point for your eligible trial below:

If you are unsure, please leave blank.

Rating your experience

This section will evaluate the website based on your experience using it. Please answer these questions in an **honest, unbiased** way.

Based on your experience of using the website, please fill in the below System Usability Scale to reflect your honest opinion – this system may be used by real patients, so evaluation and feedback are important.

Please choose your immediate thought, as opposed to thinking about answers for a long time. *

	Strongly **disagree**	**Disagree**	Neutral	**Agree**	Strongly **agree**
I think that I would like to use this system frequently.	◯	◯	◯	◯	◯
I found the system unnecessarily complex.	◯	◯	◯	◯	◯
I thought the system was easy to use.	◯	◯	◯	◯	◯
I think that I would need the support of a technical person to be able to use this system.	◯	◯	◯	◯	◯
I found the various functions in this system were well integrated.	◯	◯	◯	◯	◯
I thought there was too much inconsistency in this system.	◯	◯	◯	◯	◯
I would imagine that most people would learn to use this system very quickly.	◯	◯	◯	◯	◯
I found the system very...					

cumbersome (slow, complicated) to use.	◯	◯	◯	◯	◯
I felt very confident using the system.	◯	◯	◯	◯	◯
I needed to learn a lot of things before I could get going with this system.	◯	◯	◯	◯	◯

Which of the following describes your outcome of using the website? *

- ◯ I could not find any medical trials
- ◯ I found medical trials, but did not find any which I was eligible for
- ◯ I found a trial which I was eligible for

Comments

To finish this survey, please provide feedback for the following open-ended questions:

Putting yourself in the position of the patient, what did you like/dislike about this **method of searching for medical trials (i.e., via a website)?**

Putting yourself in the position of the patient, what did you like the most about the website?

Similarly, what gave you difficulty if anything, and what did you like the least about the website?

Finally, do you have any other feedback about the site, potentially future improvements?

Appendix C – Trial Pro Forma for Clinicians

Clinical Trial Pro Forma

Fields marked with * are required.

Main Details		
*	**Trial ID (e.g., ClinicalTrials.gov NCT number)**	
*	**Trial title** *(max 300 chars)*	
	Link to trial (e.g., ClinicalTrials.gov)	
*	**Trial description** *(max 3,000 chars)*	
*	**Trial location** *(max 300 chars)*	

Trial Files – to be sent via email	
File name in email	**Brief file description (e.g., "Trial details PDF")**

* **Specialties and Conditions** Select the appropriate check boxes	
☐ **Prostate conditions**	**Cancerous:** ☐ Advanced / metastatic ☐ Localised / early **Non-cancerous:** ☐ Benign prostatic enlargement ☐ Bladder obstruction
☐ **Bladder conditions**	**Cancerous:** ☐ Advanced / metastatic ☐ Localised – non muscle invasive ☐ Localised – muscle invasive **Non-cancerous:** ☐ Infections – UTI ☐ Bladder dysfunctions (incl. interstitial cystitis / painful bladder conditions)
☐ **Kidney conditions**	**Cancerous:** ☐ Advanced / metastatic ☐ Localised / early
☐ **Testes conditions**	**Cancerous:** ☐ Advanced / metastatic ☐ Localised / early
☐ **Penis conditions**	**Cancerous:** ☐ Advanced / metastatic ☐ Localised / early

* **Eligibility Criteria**	
Criteria type **(Exclusion / Inclusion)**	**Criteria description**

Principal Investigator and Secretary		
Principal Investigator details		
*	**Title**	☐ **Mr** ☐ **Mrs** ☐ **Ms** ☐ **Mx** ☐ **Dr** ☐ **Prof.**
*	**First name**	
*	**Surname**	
*	**Phone number**	
*	**Email address**	
Principal Investigator Secretary details		
*	**Title**	☐ **Mr** ☐ **Mrs** ☐ **Ms** ☐ **Mx** ☐ **Dr** ☐ **Prof.**
*	**First name**	
*	**Surname**	
*	**Phone number**	
*	**Email address**	

Associated research nurse – patient point of contact		
This research nurse will be the patient point of contact for this trial and will receive emails when patients send off their trial interests. NB: If this member of staff is already in the site database, only their name is required. Otherwise more information may be required.		
*	**Title**	☐ **Mr** ☐ **Mrs** ☐ **Ms** ☐ **Mx** ☐ **Dr** ☐ **Prof.**
*	**First name**	
*	**Surname**	
*	**Email address**	

Appendix D – Requirements and Development Timeframe

Feature Requirement	Start	End
CORE FUNCTIONALITY - patient trial search: • Trial search page: patient should be able to input medical specialty and subspecialty • Trial search results page: will list trials which match the search parameters from the trial search page, which are clickable and provide more information. • Trial page: this page will contain trial information. Its fields are highlighted below: • ID • Title • Associated medical specialties and subspecialties • Link to external site • Description NB: at this point, no trial management method was yet developed	21/10/2020	30/10/2020
Manage trial staff functionality: • Staff home page with link to manage trial staff • Manage trial staff page: should show a list of trial staff. Will have a button to add a new staff member, leading to the add page. An individual staff member can be modified by clicking their entry. • Add trial staff page: should allow input of clinical staff to be linked to clinical trials by their specialities. The fields include: • Title • First name • Last name • Staff role (plain text) • Phone • Email	26/10/2020	30/10/2020

• Associated medical specialties and subspecialties • View/edit trial staff page: will display all information from the add trial staff page, but can be modified and saved. Also has a button to delete the staff member record.		
Manage clinical trial functionality: • Very similar to manage staff functionality - will have manage trials page displaying trials, an add page, and a view/edit page. The fields should be the same as is shown on the patient trial page.	30/10/2020	09/11/2020
Patient trial search changes/additional functionality: • Additional medical sub-specialties required to be added as options. These should be available as options on the trial search patient page. • There should be a patient home page, instead of the trial search being the home page. This page should contain basic introductory information and a link to the trial search page. • Relevant staff to each trial should be included in the patient trial page along with their contact details.	09/11/2020	20/11/2020
Patient trial search changes/additional functionality: • Trial search needs an additional step - keyword search. Must match trials with name, description or location which match any input keywords. • Synonym system - when a patient enters a keyword to search with, any trials which contain clinician-specified synonyms of that keyword should also be shown in the results. • There should be a manage synonyms/terms page, accessible via the staff home page. This shows existing terms. • A new term can be added via a separate page, and it should be able to have multiple synonyms added and associated with it. This page should be accessible with a link via the manage synonyms/terms page. • View/edit pages will facilitate modifying or deleting terms and their synonyms, for example adding a new synonym of an existing term. This	20/11/2022	27/11/2020

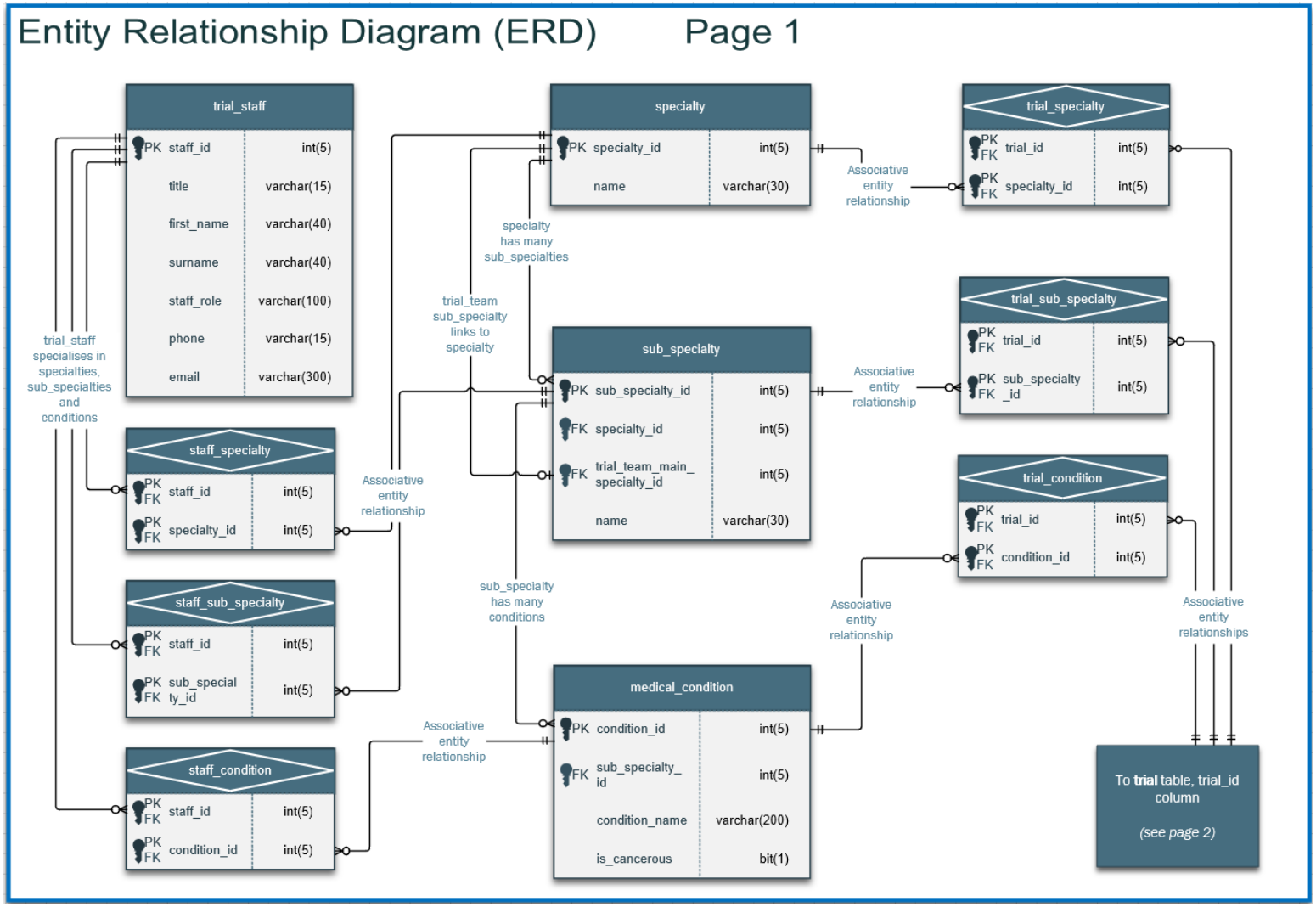
page should be accessible from the manage synonyms/terms page when clicking on a listed term.		
Eligibility criteria functionality/feature: • Each trial should list eligibility criteria on the patient trial page. Each criteria will be either inclusion or exclusion. • On the add and view/edit trial pages, staff should be able to add plain-text eligibility criteria, and mark them as either inclusion or exclusion.	27/11/ 2020	05/12/ 2020
Eligibility criteria changes/additional functionality: • On patient trial page, criteria should be presented as a step-by-step form, one criteria per step. At the end of the form, the patient should be informed if they meet the criteria or not	05/12/ 2020	15/12/ 2020
Search logs feature/functionality: • Search logs should track all details of a trial search from the trial search form, along with how many results were found. This should facilitate overseeing the success and use cases of the system. • Results should be visible on a new staff page for metrics and logs	05/12/ 2020	15/12/ 2020
Trial search and staff management changes/additional functionality: • Each trial should have specific conditions it is associated with, in addition to the medical specialties and sub-specialties. • The patient trial search form should have an additional step, for optionally selecting conditions. This should be reflected in the search results. • Trial staff records should also be associated with specific medical conditions. These can then be linked with trials using a new matching algorithm that matches based on specialties, sub-specialties, and conditions.	15/12/ 2020	26/12/ 2020
Additional data privacy and GDPR considerations and requirements, in anticipation of the application moving from proof-of-concept/research, to deployment, in the coming months: • A privacy policy should be implemented for both clinicians and patients. Cookies which are not essential should be agreed to before being used.	02/01/ 2021	14/01/ 2021

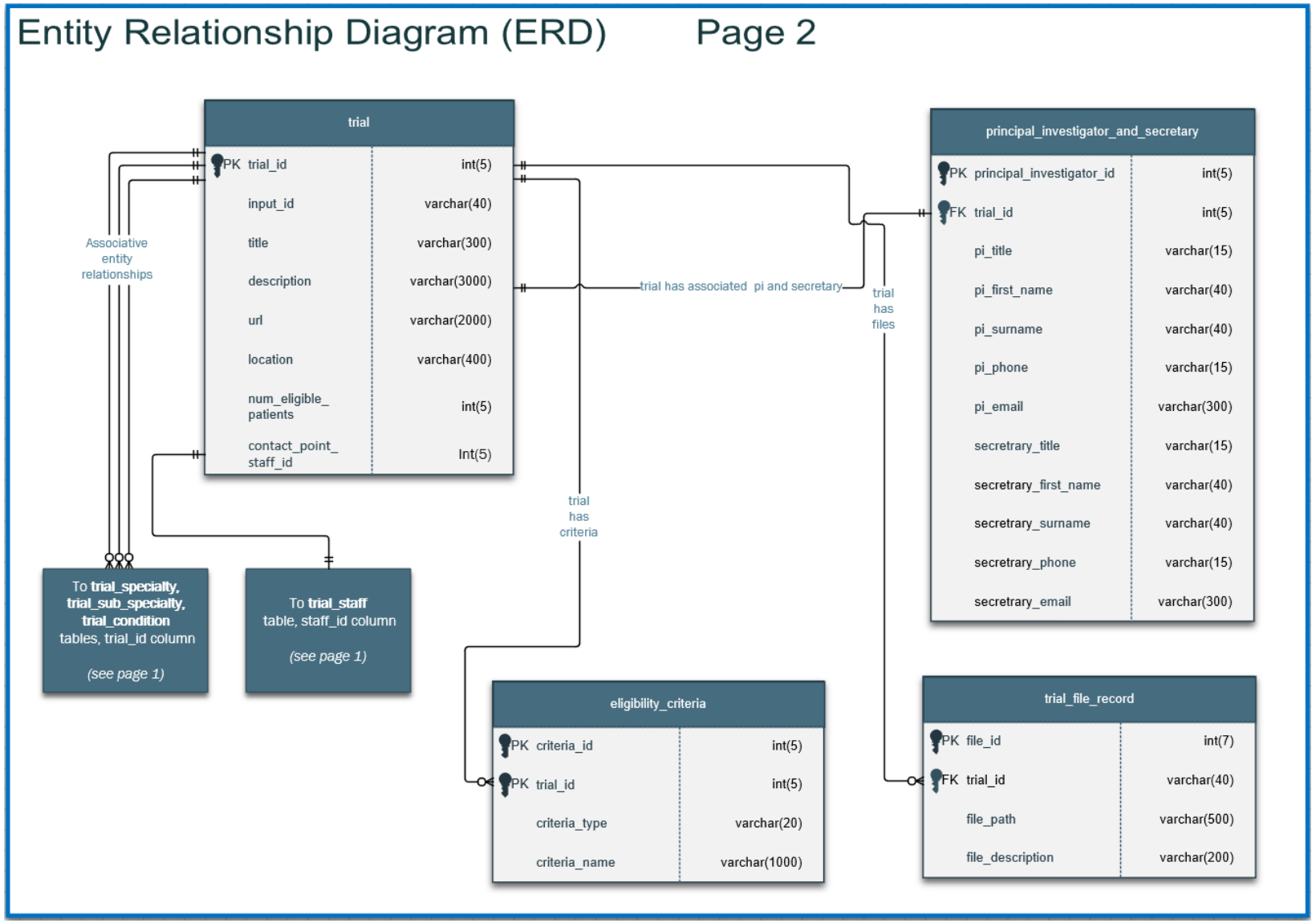
Primarily, patient trial search logs require cookie consent. • Trial search logs should hold more limited information, to make them non-sensitive and non-identifying.		
Search logs changes/additional functionality: • Trial search logs should also contain the number of trials the patient clicked on to view, and whether they found an eligible trial. This should only be applicable in browsers which have consented to the additional cookies.	02/01/ 2021	09/01/ 2021
Trial search and trial page changes/additional functionality: • Patient trial view should display the trial's location field - plain-text • Staff must be able to add the location field when creating or editing a trial • Patient trial search should require a condition be selected, as opposed to being optional. • Patient trial search should no longer require the keyword search - it should be optional.	14/01/ 2021	18/01/ 2021
Medical specialties and trials changes/additional functionality: • An additional specialty should be available on trial staff management pages - the Trials Team - reserved for research nurses. • Each trial should have a contact point associated with it - this will be one of the Trials Team. This should be selectable on the add and view/edit trials pages. The patient trial view should list this new member of staff.	18/01/ 2021	26/01/ 2021
Patient feedback survey functionality/feature: • There should be a patient feedback form with yes/no questions as a pop-up on the patient trial page. • If cookies are consented to, this survey response should be linked to the search log	18/01/ 2021	26/01/ 2021

• Survey responses should be presented textually and visually on the staff metrics and logs page		
Trial page changes/additional functionality: • The patient trial page should display the contact information of the Principal Investigator and their secretary. This contact information is: • Title • First name • Last name • Phone • Email • The Principal Investigator and their secretary should be input on the staff add and view/edit trial pages, with the same fields as listed above.	26/01/ 2021	02/02/ 2021
Patient feedback survey changes/additional functionality: • The feedback survey should be on its own page, accessible from the navigation bar of the patient portal. The pop-up on the trial page should now lead to this separate page.	02/02/ 2021	03/02/ 2021
Trial changes/additional functionality: • Staff should be able upload files along with each trial record, such as additional information, and a short description for each file. This option should be present on the add and view/edit trial pages. • These files should be available on the patient trial page to download	02/02/ 2021	11/02/ 2021
### ***Off due to illness***	12/02/ 2021	17/11/ 2021
Trial bookmarking/saving functionality/feature: • When patients complete the trial eligibility form, if eligible, and if cookies are consented to, they should be presented with the option to save this trial, or remove it if already saved. • Saved trials should be visible in a list on the "My Trials" patient page. • The patient should be able to rank trials in order of preference on the "My Trials" page, or remove them completely	18/11/ 2021	02/12/ 2021

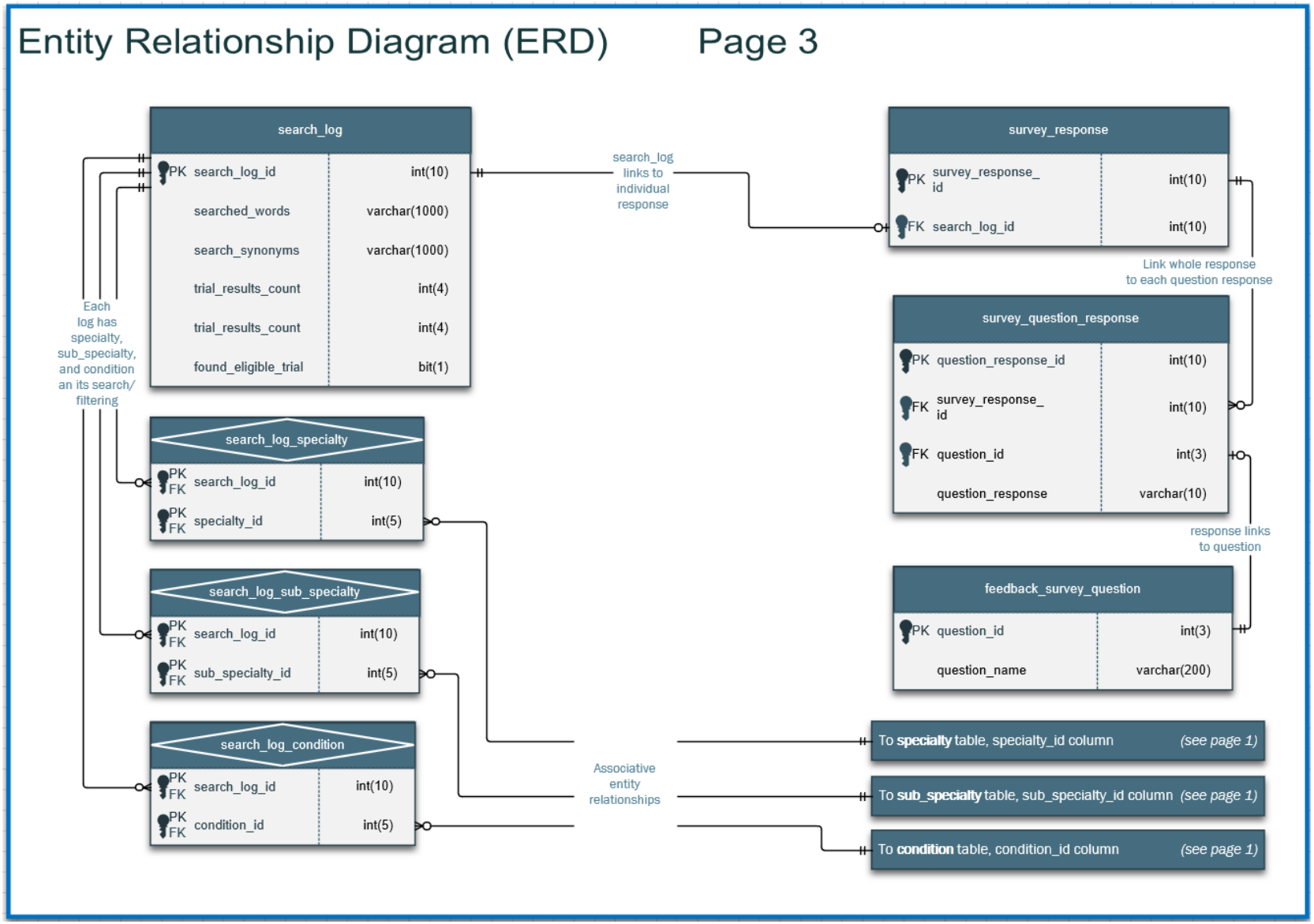
Contact staff functionality/feature: • On finding an eligible trial, patients should be able to input their contact details and send them off, to the trial's contact point by clicking a button. This will send an email informing the contact point that the patient is interested in learning more, or joining that trial. The contact details required are: • Title (required) • First name (required) • Last name (required) • Phone (required) • Email (optional) • The ability to input contact details and send to the trial staff should also be mirrored on the "My Trials" page.	02/12/2021	10/01/2022

Appendix E – Relational Database Designs

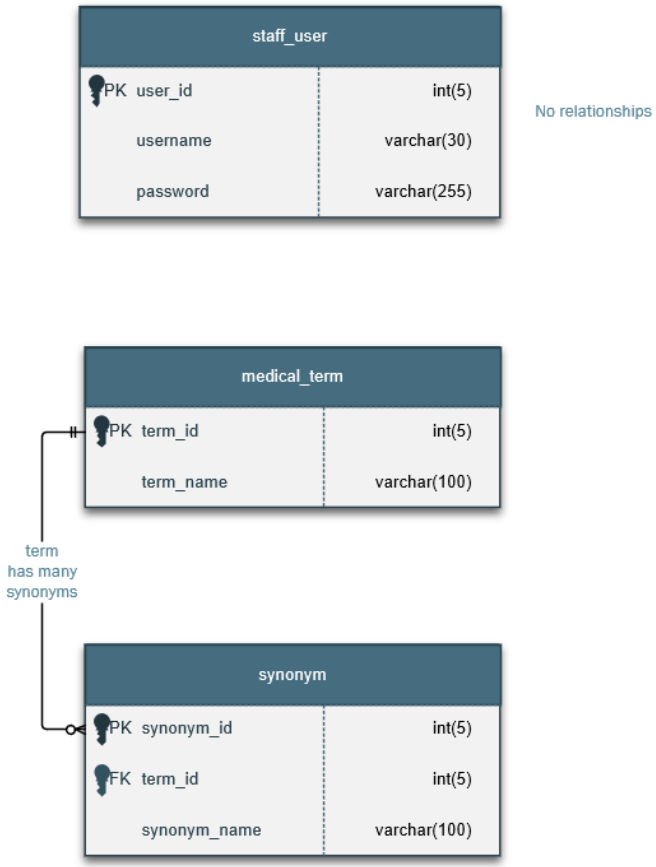



Entity Relationship Diagram (ERD) Page 2
trial
PK trial_id int(5)
input_id varchar(40)
title varchar(300)
description varchar(3000)
url varchar(2000)
location varchar(400)
num_eligible_ patients int(5)
contact_point_ staff_id Int(5)
principal_investigator_and_secretary
PK principal_investigator_id int(5)
FK trial_id int(5)
pi_title varchar(15)
pi_first_name varchar(40)
pi_surname varchar(40)
pi_phone varchar(15)
pi_email varchar(300)
secretrary_title varchar(15)
secretrary_first_name varchar(40)
secretrary_surname varchar(40)
secretrary_phone varchar(15)
secretrary_email varchar(300)
Associative entity relationships
trial has associated pi and secretary
trial has files
trial has criteria
To trial_specialty, trial_sub_specialty, trial_condition tables, trial_id column
(see page 1)
To trial_staff table, staff_id column
(see page 1)
eligibility_criteria
PK criteria_id int(5)
PK trial_id int(5)
criteria_type varchar(20)
criteria_name varchar(1000)
trial_file_record
PK file_id int(7)
FK trial_id varchar(40)
file_path varchar(500)
file_description varchar(200)

Entity Relationship Diagram (ERD) Page 3



Entity Relationship Diagram (ERD) Page 4



Appendix F – Urology Suggestions for the Website

The primary feedback from the Urology demonstration is highlighted below:

- Moving forward, the site should have a business card and/or QR code to promote it. This would be included in a patient information package/leaflet
- The facility for patients to contact trial contact points within the site was a suggestion of the Urology team following the demonstration *
- The trial ranking system was suggested by the Urology team following the demonstration *
- The trial and contextual information on the home page was suggested during the demonstration *
- The feedback survey within the site should list the number of questions it contains as part of the overview

Points marked with * were completed during the course of the MSc dissertation.

Appendix G – Patient/Public Involvement and Project Funder Feedback

Funding representatives:

- Survey questions – suggested to capture qualitative information, e.g., ask for specific improvements, along with the yes/no questions
- Moving forwards, there may be a requirement/expectation of Welsh language support
- The website is considered fully functional and complete
- Testing with a patient group would be required prior to additional funding
- The team should research if there are other similar projects that have recently appeared

Patient and Public Involvement representatives:

- The synonym addition system would be a lot of work for the administrative officer(s). It is suggested to incorporate a system to automatically load synonyms from predefined synonym dictionary / search terms.
- Future requirement - scale across organisations / hospitals:
  - Patients can search by location and/or search by “within X miles of me”
  - Trial staff should only be able to access or create trials for their own hospital/health board(s)
  - Trial and staff records would require a location field, check box or similar
- This site could possibly link to other automated data sources in the future such as Cancer Research UK (CRUK)
- Data protection / governance / GDPR: ownership of data will need further consideration at the next stage. This would include further consideration of the cookie policy and similar measures.
- The team should review with North Wales Cancer (Patient) Forum to get patient feedback

Appendix H – Site Modifications from Results

The following modifications were made to the site based on research results:

- Unnecessary contacts were removed from the trial page, leaving only the Trial Contact Point
- Contact details were moved nearer to the top of the trial page, immediately after the trial ID and specialties (shown in Figure H-1)
- Added a button link labelled “Back to trials” to the end of the eligibility form, when displaying that a user is not eligible (shown in Figure H-2). When clicked, this takes the user back to the list of trials that match their initial search results.
- Removed automatic scrolling when using buttons within the eligibility form
- Added the facility for text input questions to the feedback survey included within the site (shown in Figure H-3).

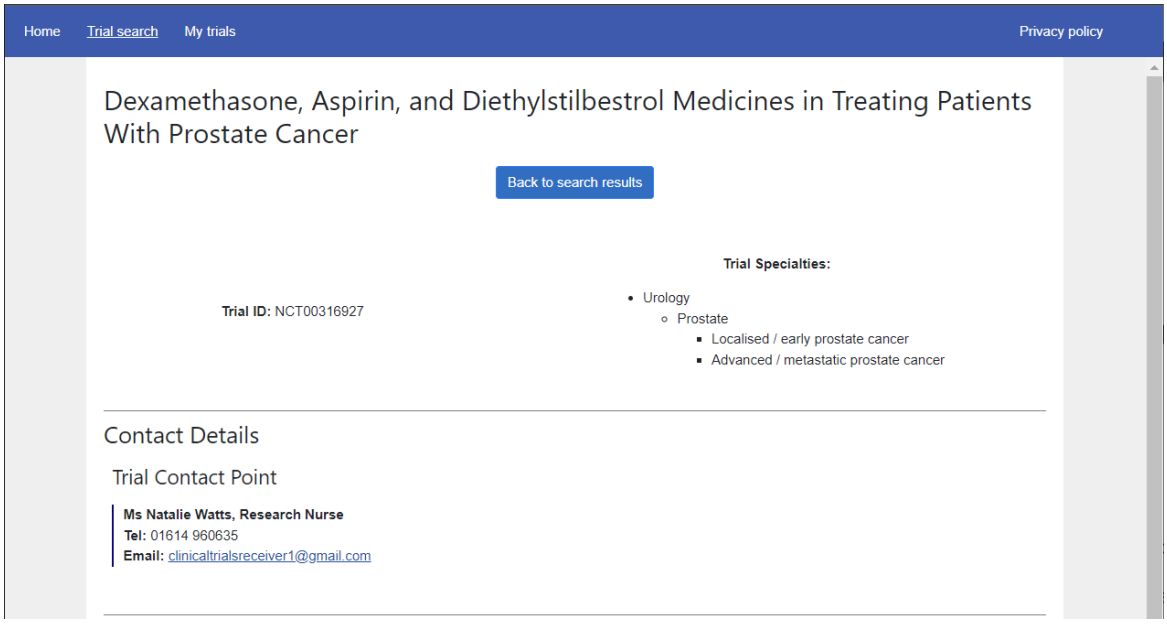


Figure H-1: Contact details

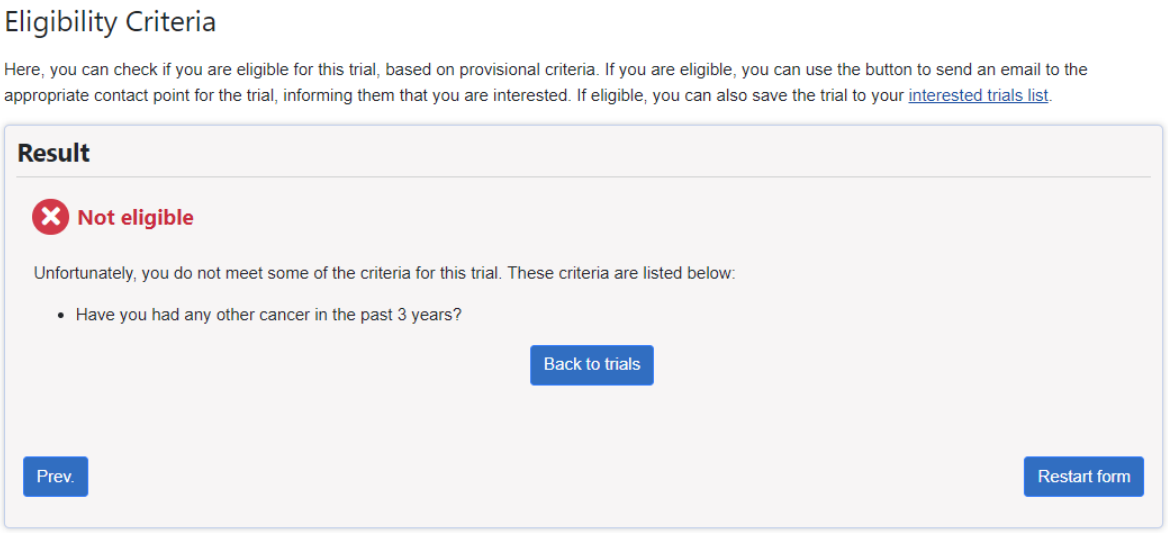


Figure H-2: “Back to trials” button

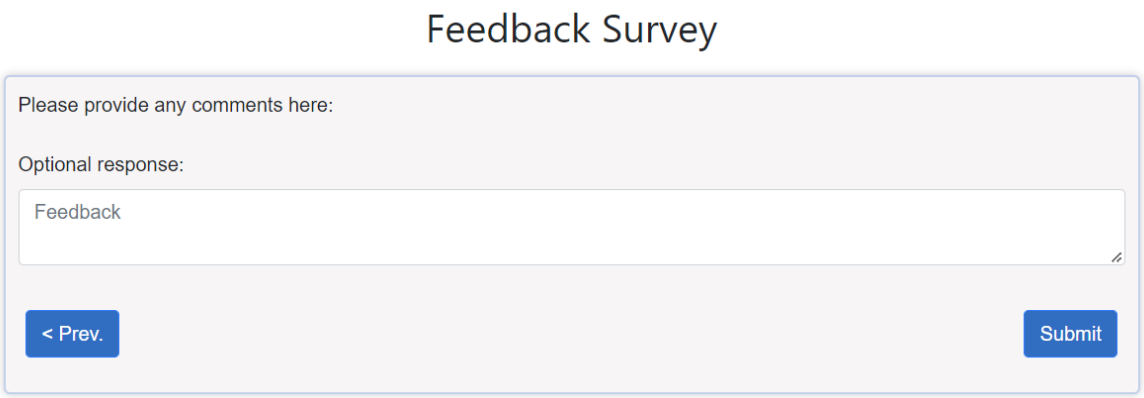


Figure H-3: Feedback survey with a text input question