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STUDY TO EVALUATE THE WILLINGNESS OF HEALTHY VOLUNTEERS, PATIENTS, DOCTORS AND PHARMACEUTICAL/BIOTECHNOLOGY INDUSTRY TO USE A PLATFORM (WEB OR APP) TO FACILITATE RECRUITMENT IN EARLY PHASE CLINICAL TRIALS (TRIALQ). A SURVEY STUDY

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ABSTRACT

Background: Different digital tools are designed to facilitate the identification, engagement, and sustained participation of individuals in research studies, but the existing evidence on its success is fragmented and often limited to specific tools or populations. As far as we know, there are no ongoing studies within Europe exploring the willingness of different stakeholders to use a platform for seeking early phase clinical trials for participation. **Objective:** To ascertain whether a platform to promote recruitment in early phase clinical trials would be considered as beneficial for general population, doctors and the pharmaceutical/biotechnological companies and obtain information for refining its features. **Material and methods:** Three different surveys were developed, specific for general population, for doctors and for pharmaceutical/biotechnology industry professionals. They included questions regarding clinical trial and clinical trial registries awareness, usefulness of the platform and the evaluation of its main characteristics. **Results:** Almost ninety percent (88.3%) of doctors, 77.8% industry and 46.6% general population reported utility in having a platform to look for early phase clinical trials to enroll. Features such as filters by pathology type and location, educational and plain language content, and a section for reporting participation experiences were the most highlighted. **Conclusion:** This is the first survey to capture the real willingness and needs of stakeholders regarding having this type of platform and can guide the design of future platforms focused on improving clinical trial recruitment. Additionally, shows how significant efforts are needed to enhance public awareness and ensure clinical trials are diverse and representative.

KEYWORDS: Recruitment, early phase, digital platform, pharmaceutical industry, biotechnology industry, researchers, doctors, clinical trials, general population, awareness.

INTRODUCTION

Clinical trials constitute the gold standard in research for assessing the safety, efficacy and effectiveness of a new drug or device in humans. Early phase clinical trials are the first step to test a new intervention after non-human studies[1] or to study the therapeutic efficacy of two medications with the same active ingredient. Recruitment rates in early phase clinical trials in Europe, among trials registered in EU-CTR have a median recruitment rate of 68%[2] which can be improved.

Early-phase clinical studies can involve recruiting either patients or healthy volunteers based on the investigational product and medical condition. Motivations and barriers diverge significantly between these groups. A systematic review, regarding healthy volunteers, by Stunkel et al[3] found that financial aspects motivated participation, but volunteers also considered risks, study goals, health benefits, social contribution, and learning. In contrast, a study developed in Brussels and Singapore focused on healthy volunteers showed their priorities were first centered on risk assessment, and after in time commitment, financial compensation, research staff competence, and the opportunity to contribute to medical research.[4]

Ethical concerns arise in studies involving healthy volunteers, as they face potential risks without guaranteed health benefits. However, Patients participating in clinical research are typically motivated by the prospect of therapeutic benefits or a desire to contribute to understanding or battling their medical condition.[5]

Even though various research methodologies, including interviews,[6] questionnaires,[7-8] analysis of clinical history data,[9] and surveys, have been employed to understand individuals' reasons for participating in clinical trials. There is a dearth of research examining the broader population's awareness of clinical trials or their knowledge of resources for seeking participation in such trials.

Strategies to enhance recruitment include multifaceted approaches involving online information dissemination, improved communication between patients and healthcare providers, and sharing trial details.[10] Efforts to disclose treatment information, engage in telephone contact, and adopt user-centered approaches in developing participant information leaflets have shown varied effectiveness in enhancing recruitment rates.[11] However, in a Cochrane study, significant challenges were encountered in identifying universally effective strategies. The study noted considerable heterogeneity among the trials and within the various strategies employed, preventing a comprehensive synthesis of results.[12]

Due to the scarcity of substantial empirical data and a comprehensive understanding of the effectiveness of resource-intensive strategies for participant recruitment and retention, digital tools are turning on as a promising option. This shift is motivated by the potential advantages these tools offer in terms of identifying, enrolling, and sustaining study participants, as highlighted in the literature.[13]

On the digital environment, there are clinical registries that serve as a resource for the dissemination of information pertaining to clinical trials, but it is noteworthy to say that their primary purpose revolves around advancing research transparency rather than fostering links between prospective participants. Additionally, the information within these registries often presents challenges in terms of comprehension for individuals without specialized knowledge in the field.[14]

Different digital tools are designed to facilitate the identification, engagement, and sustained participation of individuals in research studies. Digital recruitment strategies encompass a wide array of methods, including automated phone messaging, video content, online advertising, social media engagement, smartphone applications, volunteers registries as the Vaccelerate volunteer registry[15] and more. While various systematic reviews have assessed the effectiveness of these digital approaches, they tend to focus on specific tools or target populations, and many of them are based on outdated information. The majority of research endeavors have concentrated on the utilization of digital tools for recruitment purposes (91%), with a smaller proportion dedicated to retention strategies (19%), and a limited number exploring both aspects (10%). In terms of study designs, the prevalent approach has been observational in nature (86%), whereas randomized experiments have been comparatively less common (10%).[16]

Moreover, it has been documented that the incorporation of digital technologies into clinical trials offers a substantial opportunity to improve the inclusivity, accessibility, and efficacy of clinical research.[17] Focusing on recruitment purposes, empirical evaluations indicate that the use of digital technologies, as social media is efficacious in reaching certain groups that are hard to have access through conventional methodologies. More precisely, research has demonstrated that social media recruitment possesses the capacity to overcome linguistic and educational barriers, which results in effectively reaching immigrant populations or individuals with limited education and income.[18]

Although digital tools seem to offer potential solutions to the challenges of patient recruitment and retention in clinical trials, the existing evidence base is fragmented and often limited to specific tools or populations and although there are several platforms, including websites and applications primarily dedicated to enhancing recruitment efforts, these platforms often focus on specific medical conditions or present information directly extracted from clinical registries.

There are no ongoing studies within Europe that explore the willingness to use a platform for the purpose of seeking early phase clinical trials, gathering patient/volunteer, doctors and industry feedback, and acquiring additional knowledge about clinical trials. **Our principal objective** is to ascertain whether such a platform would be seen useful by the aforementioned stakeholders and obtain information regarding its possible main features.

METHODS

To pursuit the development of a platform where the pharmaceutical industry can publish their early phase studies, enabling both subjects and physicians to access this information, establish direct communication in case of inquiries, and offer participants feedback, we have created three questionnaires intended to discover the level of interest and utility of this type of platform by all the pertinent stakeholders.

Questionnaires design

Three distinct questionnaires were designed based on experience and the questionnaires designed by The Center for Information and Study on Clinical Research Participation, Inc.'s (CISCRP).[19] These questionnaires were intended for: Questionnaire 1: General population (healthy volunteers and having any condition), Questionnaire 2: Clinical doctors, Questionnaire 3: Pharmaceutical/biotechnological industry representatives, respectively.

Each of these questionnaires contained questions related to the inclination to use a platform for the purpose of looking for early phase clinical trials to enhance recruitment. Moreover, the questionnaires intended for general population, and

doctors also encompass questions concerning their current awareness regarding clinical trials and their eagerness to acquire further knowledge about them.

To ensure the clarity and comprehensibility of the survey, a pretest was conducted with members of the clinical trial unit of Hospital Universitario La Paz from diverse professional profiles. In total, nine subjects participated in this review process, providing valuable feedback on the language and overall understanding of the content.

Questionnaire Technical aspects

The questionnaires were created within Redcap system. For the online format, we developed the questionnaires using Redcap system and the questionnaires were provided by link or QR code. This approach ensured that the data collection process remained voluntary, with interested participants having the opportunity to contribute to the form online and in anonymous way always. Redcap guarantees a secure (installed in high security servers of Idipaz institution) and user-friendly experience, enhancing accessibility for a diverse audience.

Paper format of the questionnaires was also available and distributed for general population.

Questionnaire 1. Directed to general population, consisted of three sections:

Section 1 contained questions regarding sociodemographic characteristics as: - gender, age, educational level, income level, chronic diseases, nationality and whether they have previously heard about clinical trials.

Section 2 contained questions regarding the way subjects have previously heard about clinical trials (in case they have).

Section 3 contained questions to evaluate the utility of a platform where patients can look for clinical trials to participate and questions to evaluate the main characteristics for this platform as the utility of having a section to provide their experience feedback when participating in a clinical trial, having a direct contact to ask when doubts arise or more information is needed and to have available information in an easy-language to learn about clinical trials.

Questionnaire 2. Directed to clinical doctors, contained three sections:

The first section was related to demographic information and the second section contained questions to evaluate the previous awareness about clinical trials and registries and the third section contained questions to evaluate the utility of a platform where they can look for clinical trials to include their patients, the utility of having a direct contact to ask when doubts arise or more information is needed regarding the clinical trials and to have available information for patients in an easy-language to learn about clinical trials. Furthermore, this section explores the features of the platform that are perceived most valuable.

Questionnaire 3. Directed to pharmaceutical industry professionals contained:

Questions to evaluate the utility of a platform where patients can look for clinical trials to participate by using adapted language, the utility of having a section were subjects provide their experience feedback when participating in a clinical trial, the utility for subjects/ physicians having a direct contact to ask when doubts arise or more information is needed and to have available information in an easy-language to learn about clinical trials. Furthermore there were questions to see if they will invest in this type of platform to have their studies on it and what type of economic model they think will be the best.

The questionnaire also contained some questions regarding demographic information and about the clinical trials registries.

Sample size

Due to the lack of existing literature on this intervention, a formal calculation of the sample size was not possible to be carried out. Questionnaires regarding the pharmaceutical/biotechnological companies were completed by one individual, mainly operational or business roles, representing one company each. That is why the number of surveys equals to a company each. Questionnaires for General population and physicians are representing their selves, that is why we can appreciate higher sample size.

Data collection

Data were collected through questionnaires in Spanish. The questionnaires were available and provided by using social media, including what's app, and also in paper format (in case of general population).

Healthy volunteers and patients were recruited through acquaintances and their contacts, through direct contact in the waiting areas, of La Paz University Hospital in Madrid (Third level hospital) and in the surrounding streets. The survey for general population was also promoted by the Spanish Clinical Research Network (SCREn) and through patient associations.

For the rest of the participants, the link or QR code was distributed within the contact network of doctors, colleagues, family members and their contacts. Regarding the pharmaceutical/biotechnological industry representatives, one person per company responded the questionnaire representing their companies. They were invited to complete the online questionnaire, taking advantage of connections already established within the clinical trials unit of Hospital Universitario La Paz.The information collected on paper was transferred to the system for the analysis of the results.

Data analysis

A descriptive-univariate analysis was conducted on the variables examined in the questionnaire. Qualitative variables were expressed in both absolute and relative values, while quantitative variables were summarized using key measures of dispersion (mean, standard deviation, median, and interquartile range).

To assess the unidimensionality of the questionnaire, the following parameters/models were considered:

- The estimation of scale measures were performed using the Rasch model.
- The identification of potential subdimensions of the questionnaire were carried out through a principal component analysis (PCA).
- To evaluate the validity of questionnaire responses, the following parameters/models will were into account:
- Two or more categories were considered as a single category if the response thresholds do not differ by an amount equal to or greater than twice the sum of their standard errors (i.e., 2 standard deviations).
- To assess the reliability of the questionnaire, the following parameters/models were considered:
- Internal consistency analysis of the questionnaire were conducted using Cronbach's alpha.
- Agreement analysis was performed using Cohen's Kappa and weighted Cohen's Kappa.

Data protection

The confidentiality of the data was guaranteed in accordance with current regulations. All information obtained was treated confidentially in compliance with Organic Law 3/2018, of 5 December, 'Protection of Personal Data and

guarantee of digital rights' in compliance with Regulation European Union 2016/679 of the European Parliament and of the Council of 27 April 2016 of Data Protection.

Ethical Committee

The study was approved by the ethical committee of Hospital Universitario La Paz. The approval number is PI-6022.

Study registry

The study was publicly registered at clinicaltrials.gov prior to its commencement. The registry number is NCT06302647.

RESULTS

Results to Questioner 1. Responded by general population. (See multimedia appendix VII 1a and 1b)

As shown in table 1. A total 116 questionnaires were completed by general population of whom 67.2% were women and 32.8% were men. Regarding age distribution, the majority fell between 18 and 30 years old (34.5%) and in terms of educational level, 78.4% had university studies.

Regarding clinical trial awareness 94.0% had heard about clinical trials before this questionnaire, although only 61.2% had knowledge about early-phase clinical trials and 81.9% were not familiar with clinical trial registries. Previous participation in clinical trials was low, with 88.8% having not participated before.

The main sources of information about clinical trials were friends, acquaintances, or family members (49.1%), medical situations or healthcare professionals (44.0%), and media such as radio and television (36.2%).

Most participants expressed interest in learning more about clinical trials (67.2%) and receiving information about potential trials in which they could participate (60.3%). However, willingness to participate in early-phase clinical trials varied: 25.9% would not be willing under any circumstances, 44.8 will be willing to participate and 29.3 not sure Regarding the use of a platform to search for clinical trials, 46.6% would be willing to use it, while 35.3% would not, and 18.1% were unsure.

Table 1: Results of Questionnaire 1. Demographics part of General population responding the questionnaire.

VARIABLE	TOTAL: n (%)
Gender	
Masculine	38 (32.8)
Femenine	78 (67.2)
Age	
18 - 30 years old	40 (34.5)
31 - 45 years old	24 (20.7)
46 - 60 years old	30 (25.9)
61 - 75 Years old	14 (12.1)
Not answered	8 (6.9)
Nationality	
Spanish	114 (98.3)
Other	2 (1.7)
Educational level	
Compulsory education or lower	3 (2.6)
High school or vocational training	21 (18.1)
University studies	91 (78.4)
Not specified	1 (0.9)

Occupation	
Student	13 (11.2)
Activ worker	85 (73.3)
Not activ worker (Retired or not currently working)	18 (15.5)
Net monthly income	
<1000 euros	18 (15.5)
1000 – 1500 euros	20 (17.2)
1501 – 2000 euros	28 (24.1)
2001 – 3000 euros	29 (25.0)
> 3000 euros	17 (14.7)
Not answered	4 (3.4)
Chronic illness	
No	89 (76.7)
Yes	27 (23.3)
Have you ever heard of clinical trials prior to this questionnaire?	
No	3 (2.6)
Yes	109 (94.0)
Not sure	4 (3.4)
Have you had any knowledge about early phase clinical trials prior to this questionnaire?	
No	37 (31.9)
Yes	71 (61.2)
Not sure	8 (6.9)
Have you previously participated in this questionnaire in any clinical trial?	
No	103 (88.8)
Yes	10 (8.6)
Not sure	3 (2.6)
I've heard of clinical trials before through…	
Social Media	11 (9.5)
Internet	25 (21.6)
Radio / TV	42 (36.2)
Newspapers, magazines or books	29 (25.0)
Friends, acquaintances or relatives	57 (49.1)
A medical situation or a person working in the medical field	51 (44.0)
Other source	2 (1.7)
Never heard of clinical trials	3 (2.6)
Do you know any of the following clinical trial registries: the Spanish (REEc), the European EU CTR and/or the American (clinicaltrials.gov)? I do not know any of them	95 (81.9)
Yes	9 (7.8)
Not sure	12 (10.3)
Have you ever used any of these clinical trial registries?	
No	105 (90.5)
Yes	6 (5.2)
Not sure	5 (4.3)
Would you like to know more about Clinical Trials?	
No	15 (12.9)
Yes	78 (67.2)
Not sure	21 (18.1)
Not answered	2 (1.7)
Would you like more information about possible clinical trials in which to participate?	
No	24 (20.7)
Yes	70 (60.3)
Not sure	22 (19.0)
Would you be willing to participate in an early phase clinical trial?	
No, in no case	30 (25.9)
Yes, for first time in human trials of a new drug	7 (6.0)

Yes, to study already known drugs	28 (24.1)
Yes, for both types of drugs	17 (14.7)
I'm not sure	34 (29.3)
How willing would you be to participate in an early phase clinical trial?	
1 (Not at all willing)	18 (15.5)
2	31 (26.7)
3	41 (35.3)
4	15 (12.9)
5 (Totally willing)	6 (5.2)
Not answered	5 (4.3)
Would you use a platform (web format or app) to search for clinical trials in which you can participate?	
No	41 (35.3)
Yes	54 (46.6)
Not sure	21 (18.1)

Different univariate logistic regression models were estimated to determine the individual effect of each variable on the likelihood of being willing to use the platform. Table 2 shows the variables that were found to be significant. It was shown that the people that had previously participated in a clinical trial and that want to know more about clinical trials as well as those that indicated that they will like to participate in clinical trials where more likely to use the platform.

Table 2: General population variables associated with the willingness to use a platform for recruitment in clinical trials.

VARIABLE		**OR**	**P-value**
Gender		0.49	0.115
Age	(31 - 45)	0.65	0.442
	(46 - 60)	0.71	0.534
	(61 - 75)	1.03	0.963
Nationality		0.75	0.844
Educational Level		1.1	0.943
Occupation	Activ worker	0.86	0.819
	Not activ worker	0.32	0.171
Net monthly income	(1000 – 1500)	0.86	0.837
	(1501 – 2000)	1.02	0.983
	(2001 – 3000)	0.63	0.503
	(> 3000)	0.94	0.934
Chronic illness		0.79	0.640
Previous knowledge regarding clinical trials		0.70	0.777
Previous knowledge regarding early phase clinical trials		1.16	0.754
Previous participation in clinical trials		6.07	**0.099**
Heard of clinical trials before through…	Social Media	0.74	0.684
	Internet	1.06	0.918
	Radio / TV	0.59	0.232
	Newspapers, magazines or books	0.91	0.852
	Friends, acquaintances or relatives	1.25	0.595
	A medical situation or a person working in the medical field	1.41	0.409
Knwledge of any of the following clinical trial registries: the Spanish (REEc), the European EU CTR and/or the American (clinicaltrials.gov)		1.21	0.814
use of any of these clinical trial registries		1.58	0.607
Preference to know more about Clinical Trials		3.12	**0.053**
Preference scale to know more about Clinical Trials		2.56	**<0.001**
Preference in having more information about possible clinical trials in which to participate		11.95	**<0.001**
Willingness to participate in an early phase clinical trial (Yes VS No)		17.27	**<0.001**
Willingness to participate in an early phase clinical trial (scale)		3.15	**<0.001**

Results to Questionnaire 2. Responded by Physicians. . (See multimedia appendix VII 2a and 2b)

The sample of physicians consisted of 60 participants (Table 3), of whom 63.3% were women and 36.7% were men. Regarding the age distribution, the majority fell between 31 and 45 years old (33.3%), followed by the groups aged 61 to 75 years (35.0%) and 46 to 60 years (20.0%). Only 8.3% were in the 18 to 30 age range, with 3.3% not responding to this question. All participants were of Spanish nationality (100.0%).

Regarding the workplace, most physicians worked in hospitals (56.7%), followed by those in primary care centers (21.7%) and other types of centers (15.0%). A total of 98.3% of the physicians knew what a clinical trial was before this questionnaire. However, only 51.7% were familiar with registries such as REEc, clinicaltrials.gov, or EU-CTR.

The ability to direct a patient to a clinical trial was limited: 35.0% did not know where to search or how to guide, 35.0% did know, and 30.0% were unsure. Regarding patient inquiries about participating in clinical trials, 50.0% of the physicians had never been asked, while 25.0% had been asked but did not know how to guide, and another 25.0% had used registries to guide their patients. 78.3% of physicians had never used registries to search for clinical trials for their patients. Regarding the perception of the suitability of clinical trial registries for finding information for patients, opinions varied: 3.3% considered them not suitable (score 1), 10.0% rated them as 2, 23.3% as 3, 35.0% as 4, and 11.7% as 5 (completely suitable), with 16.7% not responding.

The vast majority (88.3%) would be willing to use a simple and user-friendly platform to search for clinical trials, while 3.3% would not, and 8.3% were unsure.

Table 3: Results to Questionnaire 2. Demographics of Physicians responding the questionnaire.

VARIABLE	TOTAL: n (%)
Gender	
Masculine	22 (36.7)
Femenine	38 (63.3)
Age	
18 - 30 years old	5 (8.3)
31 - 45 years old	20 (33.3)
46 - 60 years old	12 (20.0)
61 - 75 years old	21 (35.0)
Not answered	2 (3.3)
Nationality	
Spanish	60 (100.0)
Other	0 (0.0)
Workplace	
Primary care center	13 (21.7)
Hospital	34 (56.7)
Other	9 (15.0)
Did you know what a Clinical Trial was before this questionnaire?	
No	1 (1.7)
Yes	59 (98.3)
Do you know any of the registries such as reec, clinicaltrials.gov or EU-CTR?	
No	29 (48.3)
Yes	31 (51.7)
Would you know where to look and how to direct a potential participant to a clinical trial?	
No	21 (35.0)
Yes	21 (35.0)
Not sure	18 (30.0)

Has a patient ever asked you about the possibility of participating in a clinical trial?	
Never	30 (50.0)
Yes, but I haven't known how to guide him/her	15 (25.0)
Yes, I have used these registries	15 (25.0)
Have you ever used any of these registries to look for trials in which one of your patients might participate?	
No	47 (78.3)
Yes	13 (21.7)
From 1 to 5, how appropriate would you categorize clinical trial records for finding information for a patient?	
1 (Not at all suitable)	2 (3.3)
2	6 (10.0)
3	14 (23.3)
4	21 (35.0)
5 (Totally suitable)	7 (11.7)
Not answered	10 (16.7)
Would you use a platform that includes an Essay search engine in really simple and friendly language to search for essays for potential participants?	
No	2 (3.3)
Yes	53 (88.3)
Not sure	5 (8.3)

Regarding the doctors variables that could possibly be associated to the willingness of using a platform to search clinical trials for their patients and have educational content, it was seen that those that had a positive opinion on the adequacy in the categorization of clinical trial registries would be more willing to use the proposed platform that those that not. (See Appendix II)

Results to Questionnaire 3. Responded by Biotechnological/Pharmaceutical Industry representatives. . (See multimedia appendix VII 3a and 3b)

Regarding the industry group demographics, where the sample size is representing 9 different companies, the gender distribution was 44.4% male and 55.6% female. The age distribution showed that the majority of respondents in this group were aged 46-60 years (44.5%).

33.3% were from large biotech companies, 11.1% from small biotech companies, 33.4% from large pharmaceutical companies, 11.1% from medium-sized pharmaceutical companies, and 11.1% from small pharmaceutical companies. A majority (88.9%) were familiar with clinical trial registries and 77.8% found useful the idea of a platform to improve recruitment (See appendix I) but only 28.6% reported an affirmative response when asked about inverting on it.

It was not possible to have statically significance to associate variables with an increased likelihood of using the platform to improve recruitment for the industry group, probably due to the small sample size. (See Appendix III)

Platform characteristics

Taking into account only the questionnaires that reported that will use the platform, we analyzed the desired features to be contained in the clinical trial recruitment platform (Table 4). Opinions were also gathered from three groups: the general population (subjects), clinicians, and representatives from the pharmaceutical/biotech industry.

The use of plain language was almost universally supported by subjects (98.1%), and 85.7% of industry representatives were in favor. This feature was not applicable for clinicians.

The possibility of filter by condition or location was mostly agreed in all groups. In case of the population 100% and 94.4% respectively, valued these features. Among clinicians 98.1% and 94.3% would like the platform to have these characteristics and in the industry group, 85.7% were in favor for both.

Having educational content related to clinical trials and a section where the research results are published in plain language within the platform was also high appreciated by the population (98.1%), by clinicians (88.7%) and the industry representatives (100%).

The possibility for Subjects to Report Their Opinion and Experience was supported by 90.7% of subjects and 90.5% of clinicians. It was a bit less rated by the industry (85.7%).

For subjects, it was very relevant to have the ability to contact someone for more information (92.6%). In this sense, having a chat for communications was considered useful by 88.9% of subjects.

The ability to register for future trials was favored by 72.2% of subjects, 92.5% of clinicians, and 85.7% of industry representatives.

High difference was seen when groups were asked regarding the financial compensation as yes or no appearing in the platform. It was important for subjects (88.9%) and not too much for clinicians (69.8) and industry (71.4). This distance was also increased when the question was regarding the amount detail of the compensation. For subjects it continued being relevant (85.2) but it was less important for clinicians (64.2) and also not interesting for the industry (28.6%).

The use of AI to recommend trials received mixed responses. While 70.4% of subjects supported it, only 52.8% of clinicians and 57.1% of the industry did.

Table 4: Platform characteristics to be included in a platform to improve recruitment evaluated by all stakeholders.

Plataform Characteristics	Subjects N (%)	Clinicians N (%)	Pharma/Biotech Industry N (%)
Overall	**54 (100)**	**53(100)**	**7 (100)**
Filter per condition/pathology			
Yes	54 (100)	52 (98.1)	6 (85.7)
No	0	0	1 (14.3)
Not sure	0	1 (1.9)	0
Filter by location			
Yes	51 (94.4)	50 (94.3)	6 (85.7)
No	1 (1.9)	2 (3.8)	1 (14.3)
Not sure	2 (3.7)	1 (1.9)	0
Educational content related to clinical trials			
Yes	53 (98.1)	47 (88.7)	7 (100)
No	0	2 (3.8)	0
Not sure	2 (1.9)	4 (7.5)	0
Possibility of contacting a person to request information			
Yes	50 (92.6)	46 (86.8)	6 (85.7)
No	1 (1.9)	1 (1.9)	1 (14.3)
Not sure	3 (5.6)	6 (11.3)	0

Possibility of subjects reporting their opinion and experience when participating in a study			
Yes	49 (90.7)	48 (90.5)	5 (85.7)
No	5 (9.3)	2 (3.8)	1 (14.3)
Not sure	0	3 (5.7)	0
Chat for contact			
Yes	48 (88.9)	38 (71.7)	6 (85.7)
No	2 (3.7)	6 (11.3)	1 (14.3)
Not sure	4 (7.4)	9 (17.0)	0
Registration for future trial participation			
Yes	39 (72.2)	49 (92.5)	6 (85.7)
No	6 (11.1)	1 (1.9)	0
Not sure	9 (16.7)	3 (5.7)	1 (14.3)
Detail of financial compensation (Yes/No)			
Yes	48 (88.9)	37 (69.8)	5 (71.4)
No	1 (1.9)	3 (5.7)	0
Not sure	1 (1.9)	13 (24.5)	2 (28.6)
Detail of compensation amount			
Yes	46 (85.2)	34 (64.2)	2 (28.6)
No	4 (7.4)	6 (11.3)	1 (14.3)
Not sure	4 (7.4)	13 (24.5)	3 (42.9)
AI to recommend clinical trials to participate			
Yes	38 (70.4)	28 (52.8)	4 (57.1)
No	10 (18.5)	8 (15.1)	0
Not sure	6 (11.1)	17 (32.1)	3 (42.9)
Plain language on the platform for subjects			
Yes	53 (98.1)	NA	6 (85.7)
No	0	NA	1 (14.3)
Not sure	1 (1.9)	NA	0

DISCUSSION

In clinical trials, recruitment and retention remain critical challenges, often leading to increased costs, delays in results, and insufficient statistical power to draw significant conclusions. Existing literature, such as the systematic mapping of digital recruitment tools,[16] UK surveys on digital recruitment and evaluations by Treweek and Briel,[20] highlights the current state of digital recruitment strategies. Our study addresses a gap in existing research by evaluating the willingness to use a platform for clinical trial recruitment, considering the perspectives of subjects, clinicians, and industry representatives, something not previously explored.

In today's rapidly advancing digital landscape, the integration of digital tools into clinical trials has become increasingly prevalent**.** Digital study platforms, provide opportunities to recruit and engage study participants at any time, regardless of location. Despite their potential, few published frameworks exist to guide the development of these centralized digital research platforms.[21]

Nowadays, early stages of digital recruitment involved directing them to websites for study information and contact details. Over time, digital tools have evolved to include social media, text messaging, blogs, and mobile technologies for data collection and compliance monitoring, enhancing participant recruitment and retention. Also numerous apps are being developed by sponsors and academic institutions to help patients find relevant clinical trials, such as the National Library of Medicine Pharmaceutical Product Development's Clinical Trials app[22] but, further research is needed to determine the effectiveness of these technologies across different content, disease types, and demographic groups.[23]

Our research is in fact the first one that has taken into account the point of view of the different stakeholders: subjects, doctors and pharmaceutical industry regarding the willingness to use a platform to promote recruitment in early phases but also to evaluate the main characteristics the platform should have taking their into account their real opinion. This is the first time that has been studied if we look at the scientific publications. Furthermore, the awareness on clinical trials and the clinical trials registries was tested.

In our results, we observed that an impressive 94% of respondents reported having heard of clinical trials. This percentage is notably high compared to another study conducted in the USA, where an increase in awareness of clinical trials was observed from 68% to 74% between 2008 and 2012, showing a significant number of people lacking knowledge. [24] We might speculate that the lower awareness observed in the earlier study was due to its pre-COVID-19 timeframe. However, another study conducted in the USA (Texas) in 2022 found that only 45.8% of respondents were aware of COVID-19-related clinical trials.[25] But this rate may be attributed to the specific focus only on COVID-19 clinical trials.

Along the same lines, in our study, when we specifically inquired about early-phase clinical trials, awareness significantly decreased to 61.2%. Despite the majority being aware of clinical trials in general, many had never heard of clinical trial registries. This is particularly important because more than half of the respondents (68%), similar to the findings of a study conducted in Poland with oncology patients, [26] expressed willingness to participate in early-phase trials. However, most had only heard about them through family, friends, acquaintances, or healthcare professionals, with a substantial gap in awareness reported from media sources such as TV, radio, or social media. This indicates a considerable communication effort is still needed to ensure information is disseminated across all media channels (TV, social media, digital platforms…) to reach the widest possible audience and promote equitable access. If we do not take action on this matter, there is a risk that all subjects willing to participate do not have the information to join a clinical trial. Because if not all these subjects willing to participate do not have the information.

We saw that those who had previously participated in a clinical trial or indicated a desire to learn more about clinical trials showed a statistically significant higher inclination to use the platform to look for early phase clinical trials to participate. Nearly half of the surveyed subjects (46.6%) indicated that they would use the platform to search for clinical trials in which to participate.

In the case of the surveyed doctors, half worked in a hospital, 21.7% in primary care and the rest indicated other. It is important to highlight that although nearly all doctors knew what a clinical trial was—showing a significant difference compared to another study conducted in India where only 7.5% of the 133 interviewed doctors had received training in clinical trials [27]—only 35% of the doctors in our study knew how to direct a subject to a clinical trial. This is highly significant because it impacts not only the recruitment rates of the studies but also potential subjects who look for trials to participate, as reported by 25% of the doctors, that they were not able refer the subject to any ongoing trial because they did not know how. This is even more critical considering that early-phase studies sometimes include patients.

Perhaps this is why the vast majority of doctors (88.3%) indicated that they would use a platform to review and provide information about clinical trials to subjects.

In the case of the biotechnological/pharmaceutical industry, the respondents represented nine different companies, including both small and large enterprises. More than half (77.8%) responded positively to the usefulness of a platform to improve early-phase recruitment. However, the scenario changed abruptly when asked if their company would be willing to invest in such a platform, with affirmative responses dropping to 28.6%.Perhaps, it could be because there are some companies that currently have their own apps or webs to promote their own trials but having one platform with all trials regardless the sponsor could be beneficial for population and doctors and not having so widespread the information. It could also be due to the people interview did not have enough information just with the questionnaire to provide an affirmative answer, but nonetheless this should be further explore.

When we evaluated the main characteristics that the platform could have, all groups agreed that it was very important to filter studies by type of pathology or condition and by location, as well as having a section of training content.

Some points of disagreement between the groups were very interesting, such as the importance for the subjects and the doctors (90.7 and 90.5) of having a section for the opinion of the subjects about their experience in participating in a study, in contrast to the industry (85.7%) thoughts. It was different if we asked about having a registry of volunteers where subjects could sign up and be notified of new studies. In this case it was doctors and industry who showed more interest compared to the subjects.

When asked regarding to know the details of compensation to the subjects for the inconvenience derived from participating in a study, it was very important for the subjects but on this occasion it was less important for doctors and industry (64.2% and 28.6%). The same thing also happened when asked about the use of artificial intelligence to recommend studies, the majority of subjects (70.4%) found it useful while doctors and industry (52.8 and 57.1%) did not see it that way.

In conclusion, we can observe for the first time in Europe, taking as an example these surveys developed in Spain, the opinion of three main stakeholders who would use a platform (web or app) to improve recruitment in early phase clinical trials: Subjects, doctors and industry. For all groups, the usefulness of the platform is clear, showing that the new efforts being made in this area are well underway. Also in another study carried out in January 2023 where an app was used for recruitment, it showed good recruitment rates, also indicating that they promote recruitment and together with our results that the different stakeholders are willing to use this type of platforms.[21]

However, it is very important to give a voice to the subjects. Preferences for some of the attributes that a platform of this type should contain have been revealed in these surveys. That is why, although the sample size is limited and it is suggested to expand it to more regions in Europe, it is the first survey that shows the real opinion of the needs of the stakeholders and can be taken into account for the design of future platforms that are focused on improving recruitment in clinical trials.

Furthermore, it has also been shown that although a large part of those surveyed had heard about clinical trials at some point, very few had done so through public, accessible media that reaches everyone, such as TV, radio, social networks or even public records of essays, so it is very important to make an effort in this sense so that the clinical trials are as diverse and representative as possible.

Strengths and limitations of this study

We limited the questionnaire design to the Spanish language, meaning that the scope of the study is specific to spanish-speaking people. Although our focus was initially on the Spanish language, this was due to starting the validation process in a single language, which is more efficient. The results obtained are intended to serve as a foundation for optimizing the questionnaire, with the goal of further developing it across Europe to enhance knowledge and expertise in this area and meanwhile gaining knowledge to drive the recruitment digital tools strategy when implementing them. Another limitation could be that a significant portion of the survey was distributed via link or QR code, potentially excluding some individuals from participating.

Despite these limitations, this is the first study to assess in a single publication the three points of view of the general population, industry and healthcare professionals on the usefulness of having a free accessible platform for professionals and subjects to find information on trials in which to participate.

It also assesses the awareness not only of clinical trials but also of public clinical trials registries, which are also a tool for professionals and subjects to search for trials and which very few know about or use.

This study is a first step so that these questionnaires can be adapted in other countries to continue gaining knowledge and directing efforts in an appropriate way in future developments, taking into account the preferences of the different stakeholders involved from the beginning and trying to focus on ensuring that trial information can reach as many people and professionals as possible.

AUTHOR STATEMENT

AMB, AJC, PMA, conceptualized and designed the study. PMA, DA, MTG analyzed the data. PMA, CMR performed the investigation. PMA, CMR and DA curated the data. PMA drafted the manuscript. AMB and AJC reviewed and edited the manuscript. All authors have read and approved the published version of the manuscript.

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DECLARATION OF INTEREST

The author declares there is no conflict of interest in this study.

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Multimedia Appendix I

Table S1: Descriptive table regarding Industry demographics.

VARIABLE	CATEGORÍA	TOTAL: n (%)
Gender	Male	4 (44.4)
	Female	5 (55.6)
Edad	18 - 30 years old	0 (0.0)
	31 - 45 years old	2 (22.2)
	46 - 60 years old	4 (44.5)
	61 – 75 years old	2 (22.2)
	NA	1 (11.1)
Type of company	Biotechnological industry (large company)	3 (33.3)
	Biotechnological industry (medium company)	0 (0.0)
	Biotechnological industry (small company)	1 (11.1)
	Pharmaceutical industry (large company)	3 (33.4)
	Pharmaceutical industry (medium company)	1 (11.1)
	Pharmaceutical industry (small company)	1 (11.1)
Knowledge of any of theclinical trial registries	No	1 (11.1)
	Yes	8 (88.9)
Adecuacy of the clinical trials registries to look for clinical trials	1 (Nothing adecuate)	1 (11.1)
	2	3 (33.4)
	3	0 (0.0)
	4	2 (22.2)
	5 (Totally adecuate)	2 (22.2)
	NA	1 (11.1)
Utility of a platform including a registry of clinical trials	No	1 (11.1)
	Yes	7 (77.8)
	Not sure	1 (11.1)

Multimedia Appendix II

Table S2: Sociodemographic variables associated with the willingness to use the platform from the doctors´perspective.

VARIABLE		OR	P-value
Gender		0.41	0.438
Age		1	0.965
Nationality		-	-
Workplace	Primary care center	0.38	0.316
	Hospital	-	0.995
Knowing about clinical trials before this questionnaire		-	0.995
Knowledge of any of the clinical trials registries		1.76	0.554
Knowledge of where to look and how to direct a potential participant		-	0.996
Experience that a patient has asked you about the possibility of participating in a clinical trial		5.09	0.158
Have ever used a clinical trial registry		-	0.995
Opinion on the adequacy in the categorization of clinical trial registries (Yes/No)		3.61	**0.031**
Would you use a platform to look for clinical trials?		-	0.994

Multimedia Appendix III

Table S3: Sociodemographic variables associated with the willingness to use theplatform from the industry´s perspective.

VARIABLE	OR	P-value
Gender	4	0.355
Age	0.99	0.851
Type of company	0	0.997
Opinion on the adequacy in the categorization of clinical trial registries (Yes/No)	-	0.998
Opinion on the usefulness of a platform for early phase trials recruitment	-	0.998

Multimedia Appendix IV

Table S4: Main characteristics for a platform to improve recruitment rates inearly phase trials evaluated from the general population perspective.

VARIABLE		TOTAL: n (%)
Purpose for which they would use the platform	Find a trial to participate	15 (27.8)
	Search generic informationabout clinical trials	16 (29.6)
	Find trials for a familymember or friend	13 (24.1)
	Register as a volunteer to receive notifications about trials where to participate in	9 (16.7)
	Other	1 (1.9)
Have educational content	No	0 (0.0)
	Yes	53 (98.1)
	Not sure	2 (1.9)
Relevance of the educational content	1 (Not important)	0 (0.0)
	2	1 (1.9)
	3	10 (18.5)
	4	19 (35.2)
	5 (Very important)	22 (40.7)
	Not answered	2 (3.7)
Filter according to type of condition/disease	No	0 (0.0)
	Yes	54 (100.0)
	Not sure	0 (0.0)
Filter by location	No	1 (1.9)
	Yes	51 (94.4)
	Not sure	0 (0.0)
	Not answered	2 (3.7)
Section to give opinion and report participation experience	No	5 (9.3)
	Yes	49 (90.7)
	Not sure	0 (0.0)
Willingness to report yourexperience participating in a clinical trial	1 Not at all	1 (1.9)
	2	2 (3.7)
	3	11 (20.4)
	4	12 (22.2)
	5 Totally willing	26 (48.1)
	Not Answered	2 (3.7)
Importance of knowing if thereis economic compensation	No	4 (7.4)
	Yes	48 (88.9)
	Not sure	1 (1.9)
	Not answered	1 (1.9)
Importance of detailing the amount or form ofcompensation	No	4 (7.4)
	Yes	46 (85.2)
	Not sure	4 (7.4)
Importance of detailing the amount or form ofcompensation (Scale)	1 (Not important)	2 (3.7)
	2	2 (3.7)

	3	16 (29.6)
	4	11 (20.4)
	5 (Very important)	21 (38.9)
	Not anwered	2 (3.7)
Using a personal contact to resolve doubts	No	1 (1.9)
	Yes	50 (92.6)
	Not sure	3 (5.6)
Using a chat to resolve doubts	No	2 (3.7)
	Yes	48 (88.9)
	Not sure	4 (7.4)
Most suitable option to contactwithin the application	Chat	11 (20.4)
	Message form	4 (7.4)
	Personal contact	16 (29.6)
	All	23 (42.6)
	None	0 (0.0)
Registration as a volunteer onthe platform for information about future trials to participate	No	6 (11.1)
	Yes	39 (72.2)
	Not sure	9 (16.7)
Use of Artificial Intelligence within the platform	No	10 (18.5)
	Yes	38 (70.4)
	Not sure	6 (11.1)
Section with information aboutthe results of the study	No	0 (0.0)
	Yes	53 (98.1)
	Not sure	1 (1.9)
Entering health-related data (analytics, data…)	No	10 (18.5)
	Yes	39 (72.2)
	Not sure	5 (9.3)
Global interest in the use of the platform	No	3 (5.6)
	Yes	51 (94.4)

Multimedia Appendix V

Table S5: Main characteristics for a platform to improve recruitment rates in early phase trials evaluated from the doctors perspective.

VARIABLE	CATEGORÍA	TOTAL: n (%)
Filter according to type of condition/disease	No	0 (0.0)
	Yes	52 (98.1)
	Not sure	1 (1.9)
Filter by location	No	2 (3.8)
	Yes	50 (94.3)
	Not sure	1 (1.9)
Educational content for the general population	No	2 (3.8)
	Yes	47 (88.7)
	Not sure	4 (7.5)
Educational content for healthcare professionals	No	1 (1.9)
	Yes	49 (92.5)
	Not sure	3 (5.7)
Participant´s section to give opinion and report experience in a clinical trial	No	2 (3.8)
	Yes	19 (35.8)
	Si, pero solo si fuera anónimo	29 (54.7)
	Not sure	3 (5.7)
Relevance of the section for participants to report their experience	1 (Not important)	1 (1.9)
	2	2 (3.8)
	3	13 (24.5)
	4	17 (32.1)
	5 (Very important)	13 (24.5)
	NA	7 (13.2)

Using a chat to resolve doubts	No	6 (11.3)
	Yes	38 (71.7)
	Not sure	9 (17.0)
Relevance of having a chat to resolve doubts	1 (Not important)	2 (3.8)
	2	6 (11.3)
	3	12 (22.6)
	4	12 (22.6)
	5 (Very important)	15 (28.3)
	NA	6 (11.3)
Using contact with a person to resolve doubts	No	1 (1.9)
	Yes	46 (86.8)
	Not sure	6 (11.3)
Most suitable option to contact within the platform	Chat	13 (24.5)
	Message form	16 (30.2)
	Personal contact	8 (15.1)
	All above mentioned	16 (30.2)
Importance of knowing if there is economic compensation	No	3 (5.7)
	Yes	37 (69.8)
	Not sure	13 (24.5)
Importance of detailing the amount or form of compensation	No	6 (11.3)
	Yes	34 (64.2)
	Not sure	13 (24.5)
Importance of detailing the amount or form of compensation (Scale)	1 (Not relevant)	2 (3.8)
	2	9 (17.0)
	3	23 (43.4)
	4	4 (7.5)
	5 (Very relevante)	8 (15.1)
	NA	7 (13.2)
Registration for subjects on the platform for information about future trials	No	1 (1.9)
	Yes	49 (92.5)
	Not sure	3 (5.7)
Use of Artificial Intelligence	No	8 (15.1)
	Yes	28 (52.8)
	Not sure	17 (32.1)
Using this platform to find and offer trials to your patients	No	3 (5.7)
	Yes	46 (86.8)
	Not sure	4 (7.5)
Degree of willingness to use this platform	1 (Not at all)	1 (1.9)
	2	4 (7.5)
	3	16 (30.2)
	4	16 (30.2)
	5 (Frequently)	10 (18.9)
	NA	6 (11.3)
Frequency of use of this platform	Probably never	13 (24.5)
	Once a year	4 (7.5)
	Once every 6 months	14 (26.4)
	Once every 3 months	12 (22.6)
	Once a month	10 (18.9)

Multimedia Appendix VI

Table S6: Main characteristics for a platform to improve recruitment rates inearly phase trials evaluated from the doctors perspective.

VARIABLE	CATEGORÍA	TOTAL: n (%)
Filter according to type of condition/disease	No	0 (0.0)
	Yes	52 (98.1)
	Not sure	1 (1.9)
Filter by location	No	2 (3.8)
	Yes	50 (94.3)
	Not sure	1 (1.9)
Educational content for the general population	No	2 (3.8)
	Yes	47 (88.7)
	Not sure	4 (7.5)
Educational content forhealthcare professionals	No	1 (1.9)
	Yes	49 (92.5)
	Not sure	3 (5.7)
Participant´s section to giveopinion and report experience in a clinical trial	No	2 (3.8)
	Yes	19 (35.8)
	Si, pero solo si fuera anónimo	29 (54.7)
	Not sure	3 (5.7)
Relevance of the section forparticipants to report their experience	1 (Not important)	1 (1.9)
	2	2 (3.8)
	3	13 (24.5)
	4	17 (32.1)
	5 (Very important)	13 (24.5)
	NA	7 (13.2)
Using a chat to resolve doubts	No	6 (11.3)
	Yes	38 (71.7)
	Not sure	9 (17.0)
Relevance of having a chat to resolve doubts	1 (Not important)	2 (3.8)
	2	6 (11.3)
	3	12 (22.6)
	4	12 (22.6)
	5 (Very important)	15 (28.3)
	NA	6 (11.3)
Using contact with a person to resolve doubts	No	1 (1.9)
	Yes	46 (86.8)
	Not sure	6 (11.3)
Most suitable option to contact within the platform	Chat	13 (24.5)
	Message form	16 (30.2)
	Personal contact	8 (15.1)
	All above mentioned	16 (30.2)
Importance of knowing if there is economiccompensation	No	3 (5.7)
	Yes	37 (69.8)
	Not sure	13 (24.5)
Importance of detailing the amount or form ofcompensation	No	6 (11.3)
	Yes	34 (64.2)
	Not sure	13 (24.5)
Importance of detailing the amount or form ofcompensation (Scale)	1 (Not relevant)	2 (3.8)
	2	9 (17.0)
	3	23 (43.4)
	4	4 (7.5)
	5 (Very relevante)	8 (15.1)
	NA	7 (13.2)
Registration for subjects onthe platform for information about future trials	No	1 (1.9)
	Yes	49 (92.5)

	Not sure	3 (5.7)
Use of Artificial Intelligence	No	8 (15.1)
	Yes	28 (52.8)
	Not sure	17 (32.1)
Using this platform to find andoffer trials to your patients	No	3 (5.7)
	Yes	46 (86.8)
	Not sure	4 (7.5)
Degree of willingness to use this platform	1 (Not at all)	1 (1.9)
	2	4 (7.5)
	3	16 (30.2)
	4	16 (30.2)
	5 (Frequently)	10 (18.9)
	NA	6 (11.3)
Frequency of use of this platform	Probably never	13 (24.5)
	Once a year	4 (7.5)
	Once every 6 months	14 (26.4)
	Once every 3 months	12 (22.6)
	Once a month	10 (18.9)