Queen Mary University of London

PROMiSe

PROMiSe Study Workshop
User Acceptability

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How did we identify potential patients?

Each clinical trials unit contacted their patient and public involvement group (PPI) coordinator with the information about the PROMiSe study to be sent to all members of the group. The information contained the details and purpose of the study and contact details for the trial manager at each unit to be contacted if the PPI members were interested to join the study. Once expression of interest was received by each trial manager they then sent invitations to join the study from REDCAP system. In total 86 invitation were sent in January 2018.

Which clinical trials units take part in this study?

- Pragmatic Clinical Trials Unit (PCTU), Trial Manager: Shiva Taheri
- Birmingham Clinical Trials Unit (BCTU), Trial Manager: Sarah Marium Khan
- Edinburgh Clinical Trials Unit (ECTU), Trial Manager: Kat Oatey

Which PPI groups did we approach?

- Birmingham Elders
- Bowel & Cancer Research Charity
- Asthma UK Centre for Applied Research
- A diverse surgical outpatient group from Barts Health NHS Trust
- A selection of clinical trials unit researchers

Which system did we use to collect data?

- REDCAP system was used to collect the data. REDCAP is a safe data collection system that allows patients to log in and enter their data directly.
- REDCap is free to use, thus it is a cost-effective option.
- The system is compliant with research information governance requirements, is secure and encrypted, has real time data entry validation, a full audit trail as well as an electronic signatures module and linkage with several common statistical packages for data analysis.
- We tested the system to ensure that surveys are sent at the correct time intervals in the test server before the system went live. The testing was completed in December 2017 and it went live in January 2018.

Setting up the PROMiSE platform

- The PROMISE platform includes four modules:
- 1. Online participant information sheets and consent forms.
- 2. Identifiable data (email address and NHS number required for future data linkage).
- 3. EQ-5D questionnaire.
- 4. User acceptability questionnaire.

The consent form, questionnaires and timings were set up on the system and tested to ensure the system is fit for purpose.

How did we do the user testing?

- A survey invitation was sent to participants by the trial manager at each clinical trials unit via email, which contained a link to the electronic participant information sheet and consent form (e-ICF).
- After online consent was obtained, the data was passed to the coordinating clinical trial unit.
- An EQ-5D questionnaire was sent to volunteers automatically from the PROMiSE platform and collected every 4 weeks for 6 months, in order to accumulate an extended time series of outcomes for each individual within the short duration of this study.
- On completion of the time series, a thank-you email was sent along with an acceptability questionnaire to assess user satisfaction, and exploring reasons for any non-compliance and possible improvements.

PROMiSe eCRF Workflow

- A survey invitation was sent to potential

Data Collection Instrument	PROM1 (1)	PROM2 (2)	PROM3 (3)	PROM4 (4)	PROM5 (5)	PROM6 (6)	PROM7 (7)
Study ID	○						
Eicf (survey)	○						
Uk English Eq5d5l Redcap Self Complete Web (survey)	○						
Uk English Eq5d5l Redcap Self Complete Web 2 (survey)		○	○	○	○	○	○
Acceptability Questionnaire (survey)	○						
Acceptability Questionnaire 3m (survey)				○			
Acceptability Questionnaire 6m (survey)							○

Problems we faced with REDCap survey completion

- We noticed that some of the emails sent from the REDCap system went to participants' junk mail box. We advised our participants to check their junk email and ensure to mark the email as safe to prevent the same thing happening in future. A solution for future studies could be to send the email from a personal QMUL or NHS email account rather than a generic account.
- The signature function for the consent form can only be done using a PC. Anyone trying to sign the consent form using an iPad, iPhone or tablet will not be able to sign the form.

Consent form

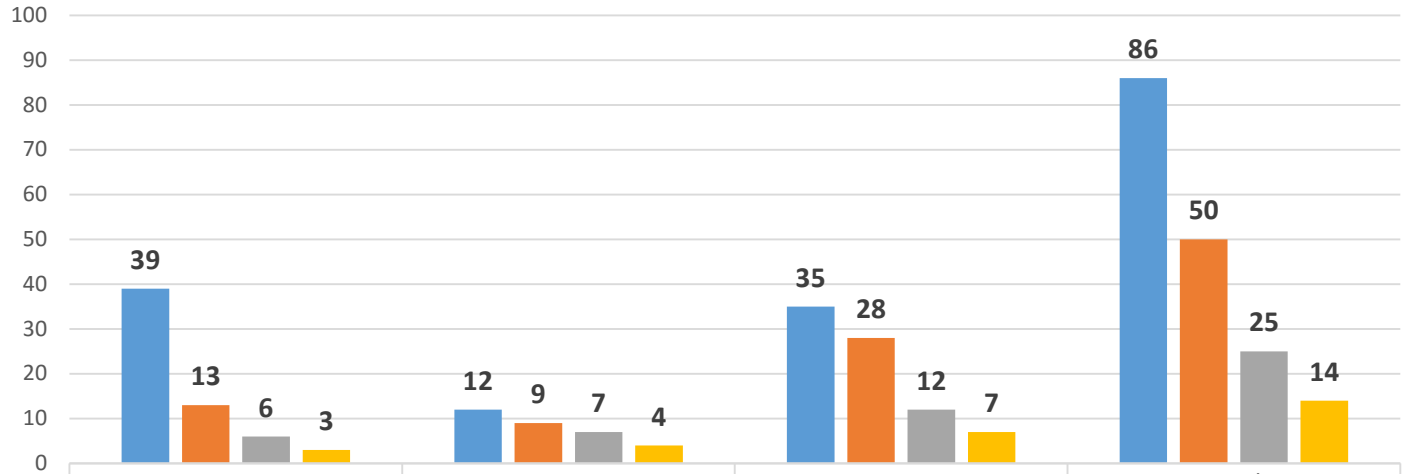
Agreement to Participate

- Thank you for agreeing to take part in the PROMiSe study. We now need you to complete the consent form below, after which you will receive your first survey.
- Agreement: I agree to take part in the PROMiSe study
- Involvement: I understand that by agreeing to take part, I will be sent an email asking me to complete online surveys every month for 6 months
- Withdrawal: I understand I am free to withdraw at any time if I wish and do not need to give a reason.
- Confidentiality: I understand that my information will remain confidential
- Results: I understand that the results of the study will be published and used to help design future research. I agree it is important for researchers to access Yes patient medical records for the purposes of No research.
- I would be willing to provide my medical record number (NHS number or CHI number) for research purposes. Yes/ No
- I know my medical record number (NHS number or CHI Yes number). No Medical record number if known (NHS or CHI number).

Demographics

- Age I am age 18-25 I am age 26-40 I am age 41-65 I am age 66-80 I am over 80
- Gender Male Female Prefer not to say
- Membership Birmingham Elders PPI Group Bowel & Cancer Research Charity PPI Group Asthma UK PPI Group Research Community Carer Other
- Consent
- First Name _____ Surname _____ Email _____Date _____Signature

PROM1, PROM4, PROM7 Response Rate by Site



	BCTU	ECTU	PCTU	Total
Invitations Sent (PROM1)	39	12	35	86
Response (PROM1, Month 1)	13	9	28	50
Response (PROM4, Month 3)	6	7	12	25
Response (PROM7, Month 6)	3	4	7	14

EQ5D questionnaire contents

- EQ5D is a standardised questionnaire for measuring generic health status. The questionnaire comprises five dimensions:

➢ Mobility

➢ Self-care

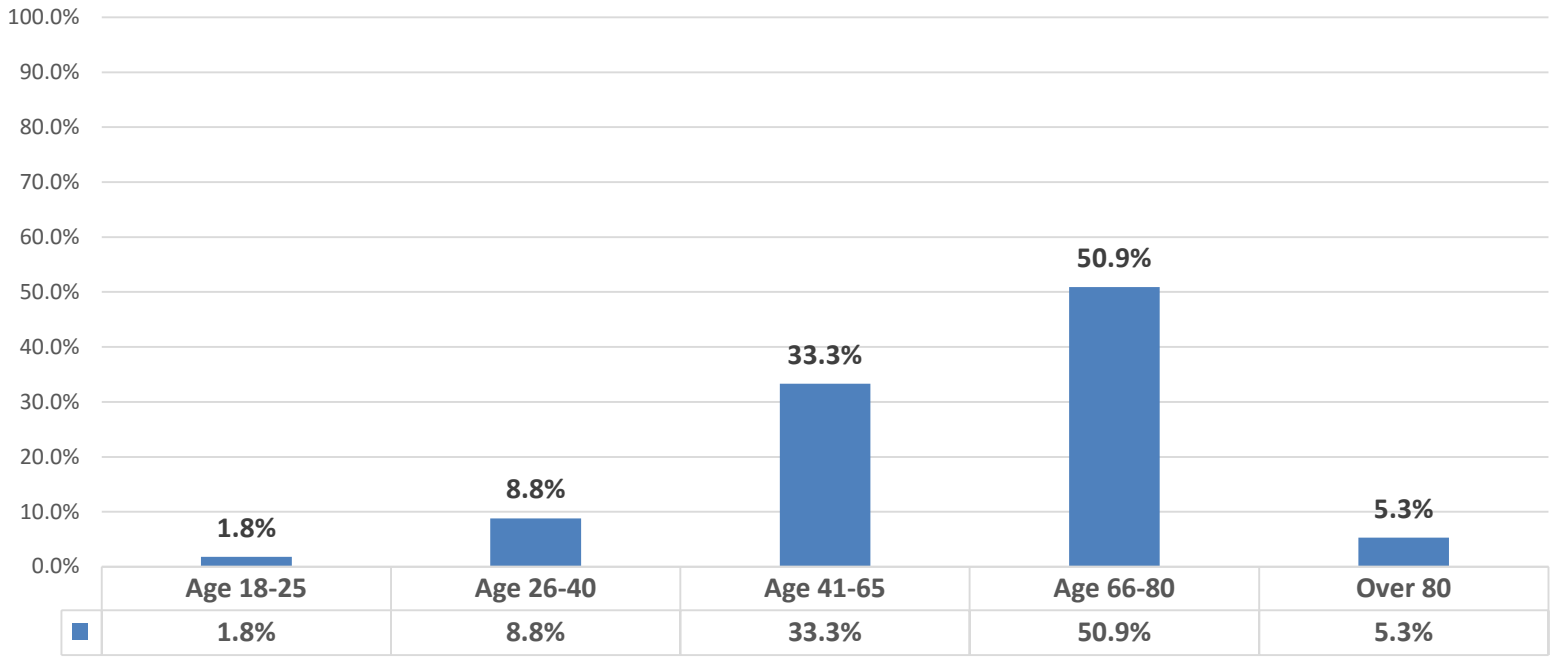
➢ Usual activities

➢ Pain/discomfort

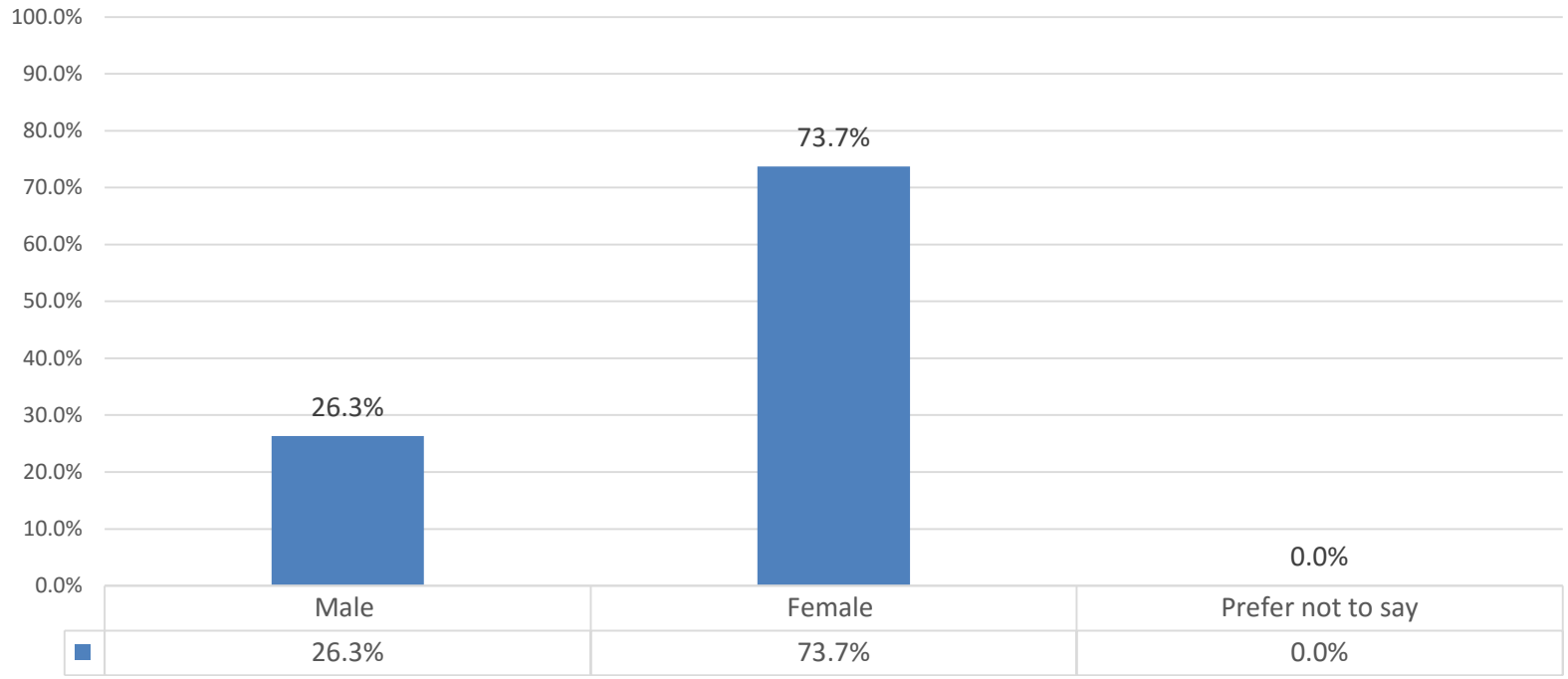
➢ Anxiety/depression

- Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems. The patient is asked to indicate his/her health state by ticking the box next to the most appropriate statement in each of the five dimensions.

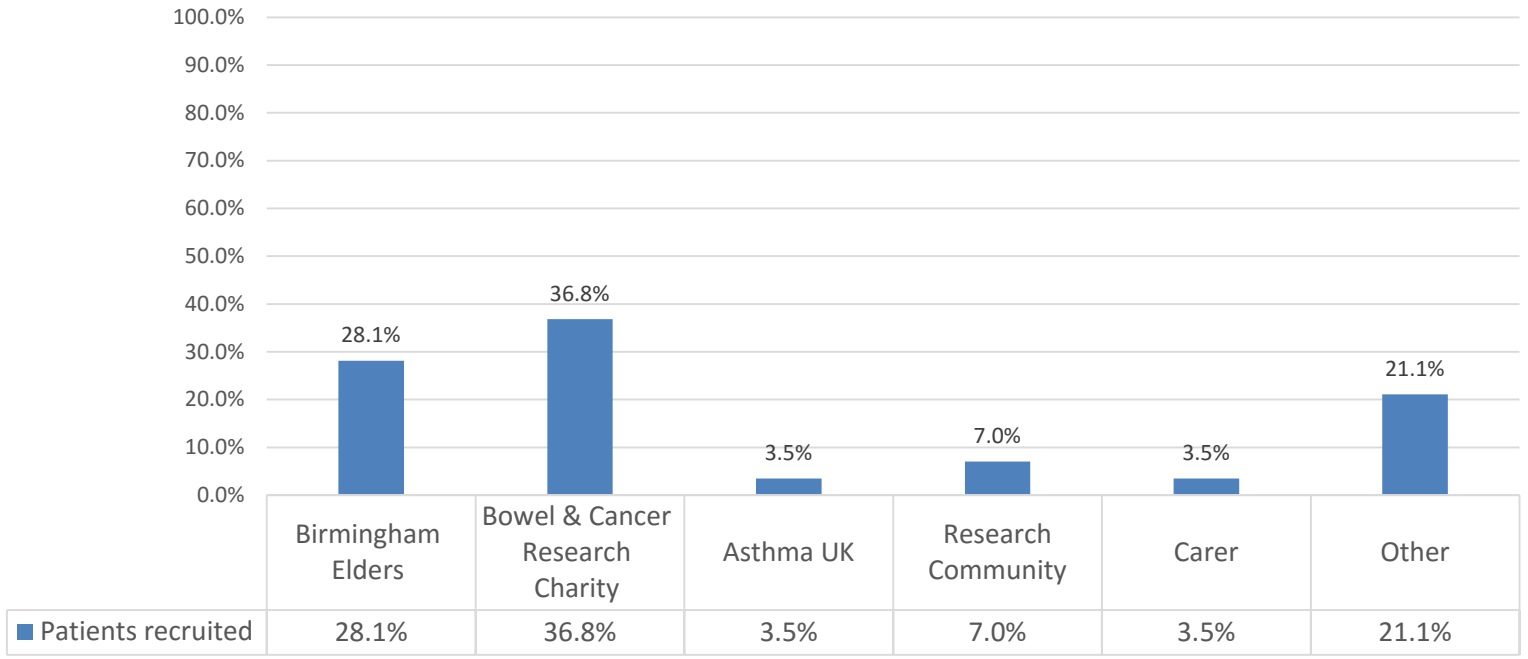
Demographics: Age



Gender


100.0%
90.0%
80.0%
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
26.3%
73.7%
0.0%
Male
Female
Prefer not to say
26.3%
73.7%
0.0%

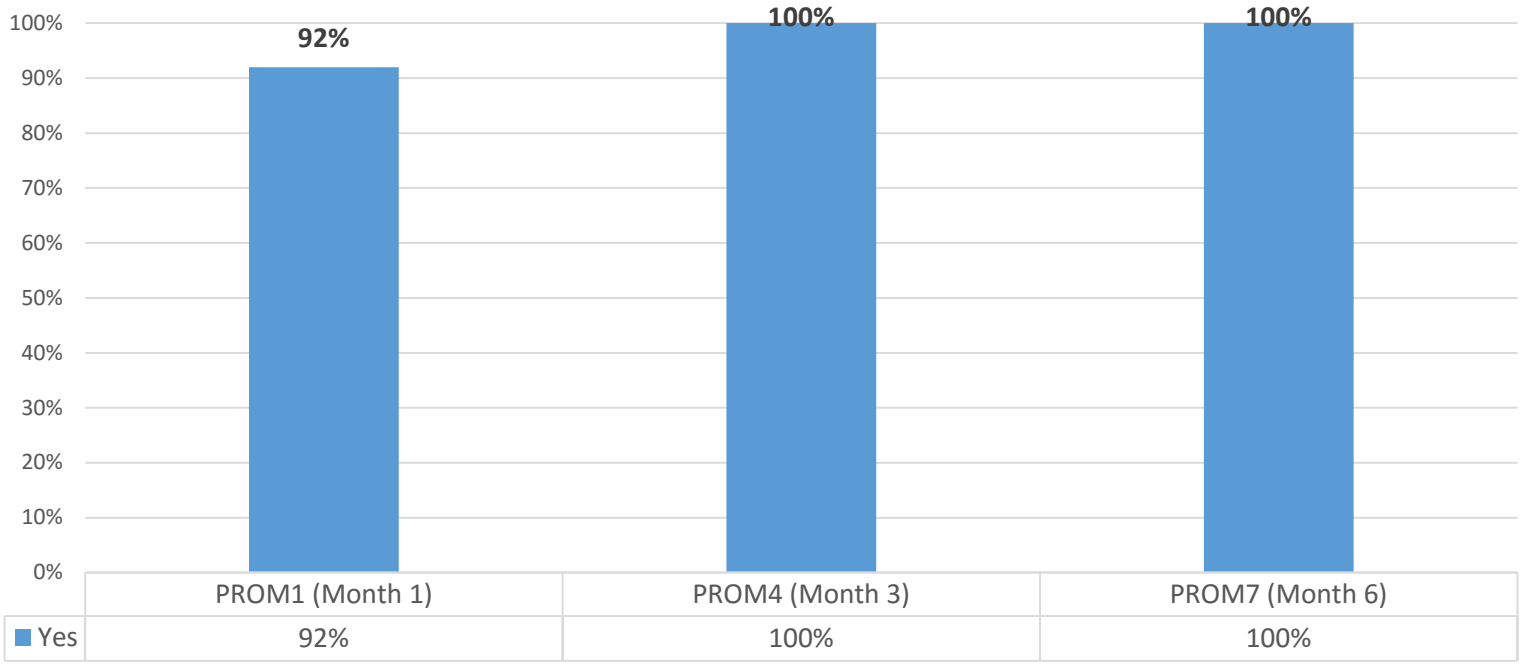
Membership



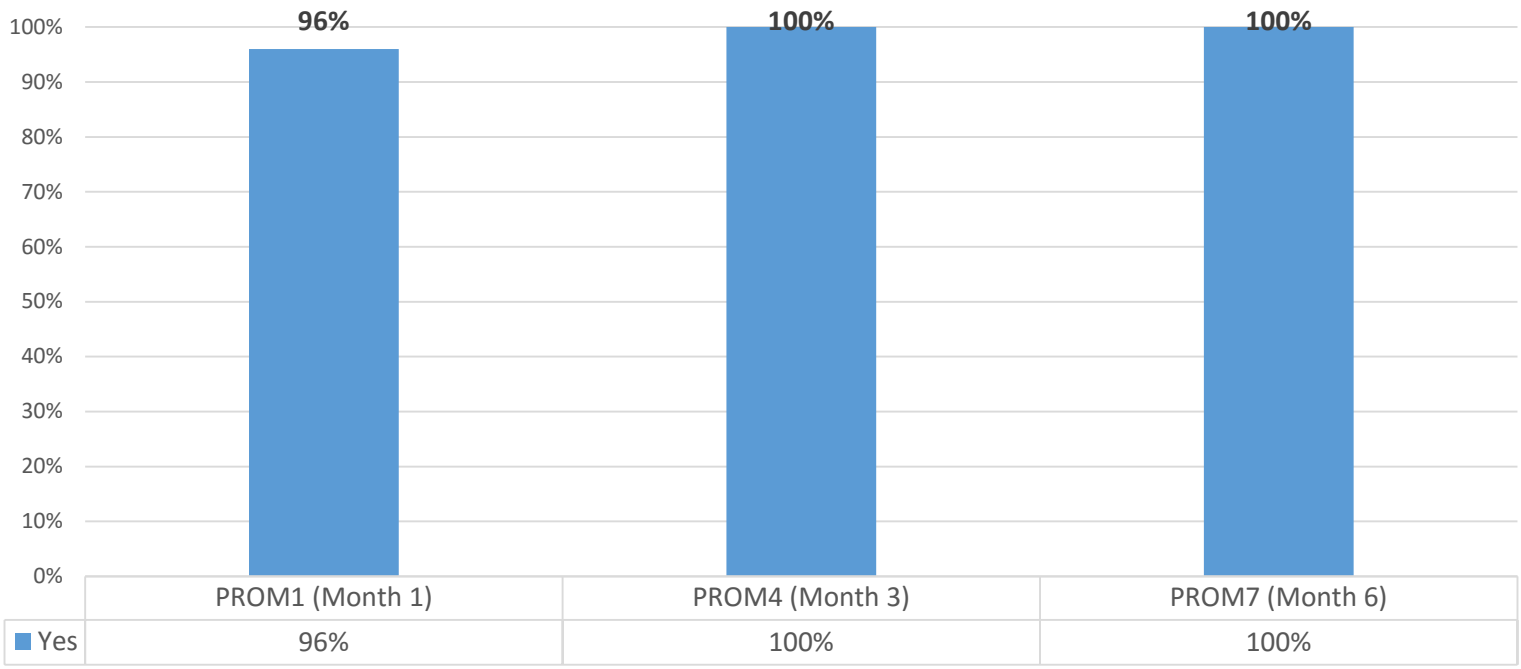
	Birmingham Elders	Bowel & Cancer Research Charity	Asthma UK	Research Community	Carer	Other
Patients recruited	28.1%	36.8%	3.5%	7.0%	3.5%	21.1%

Acceptability Questionnaire

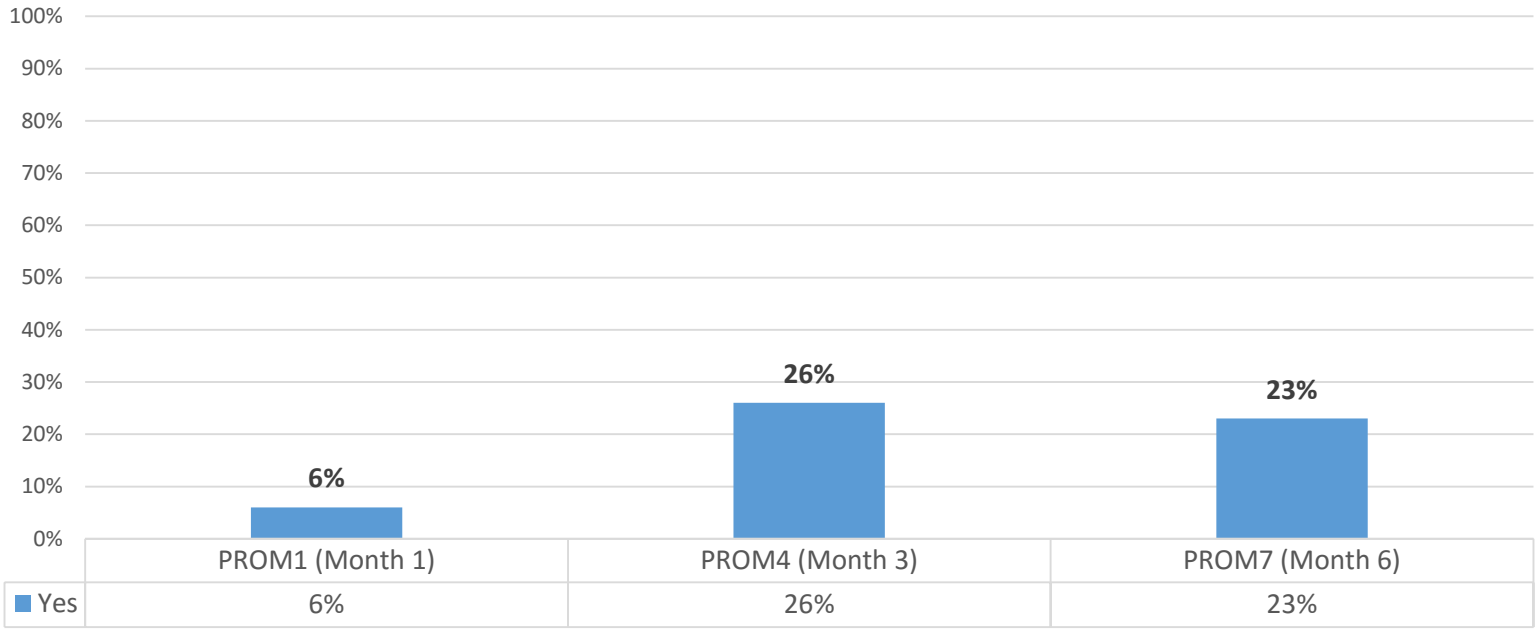
Did you find the method of online consent acceptable?



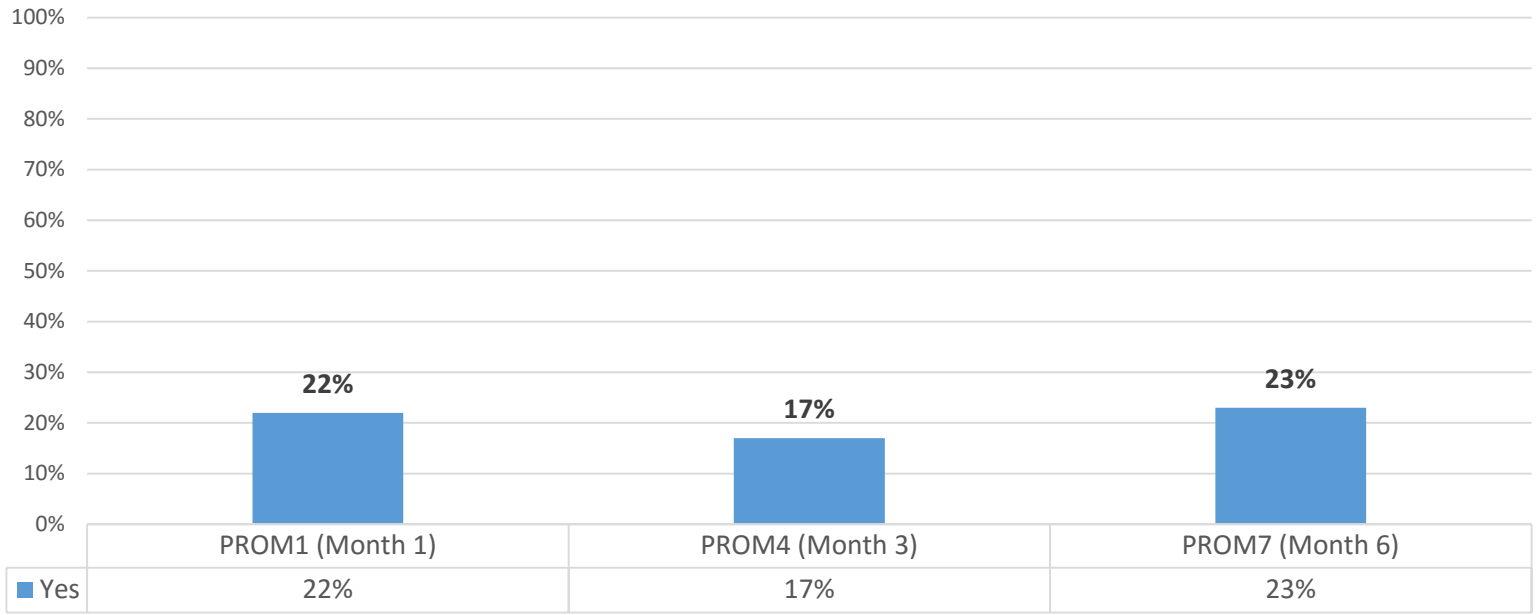
Was the information provided clear and sufficient enough for you to fully understand what was required to take part?



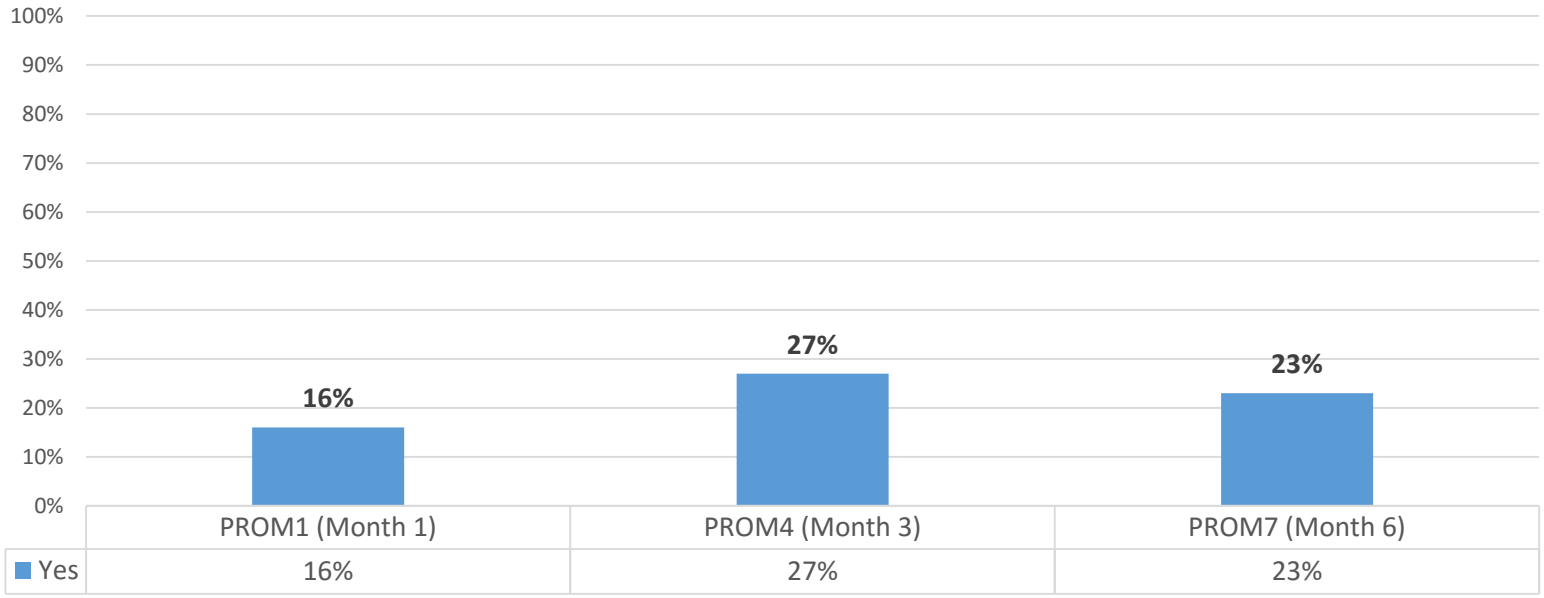
Would you have preferred to speak to one of the researchers organising this study before agreeing to take part?



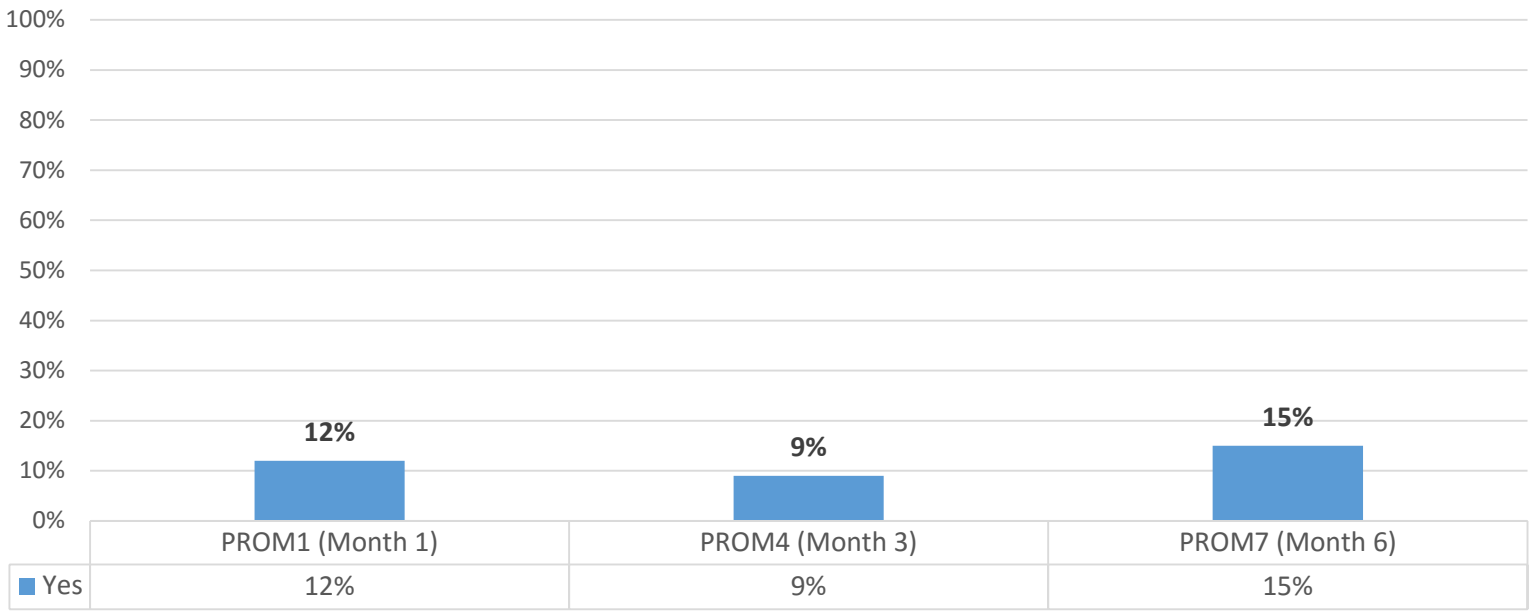
Are you concerned about your data security?



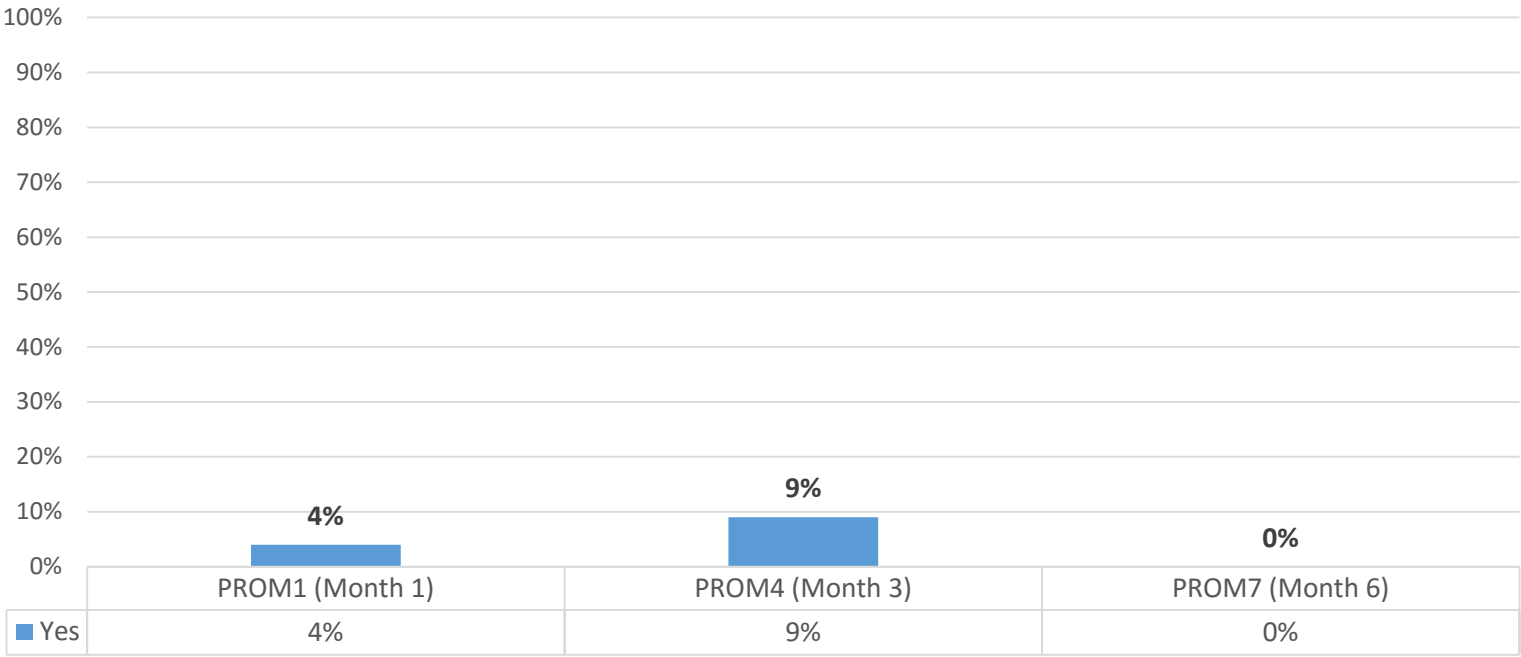
Are you concerned about sharing your personal information such as name and/or medical record number (i.e. NHS or CHI number) with us?



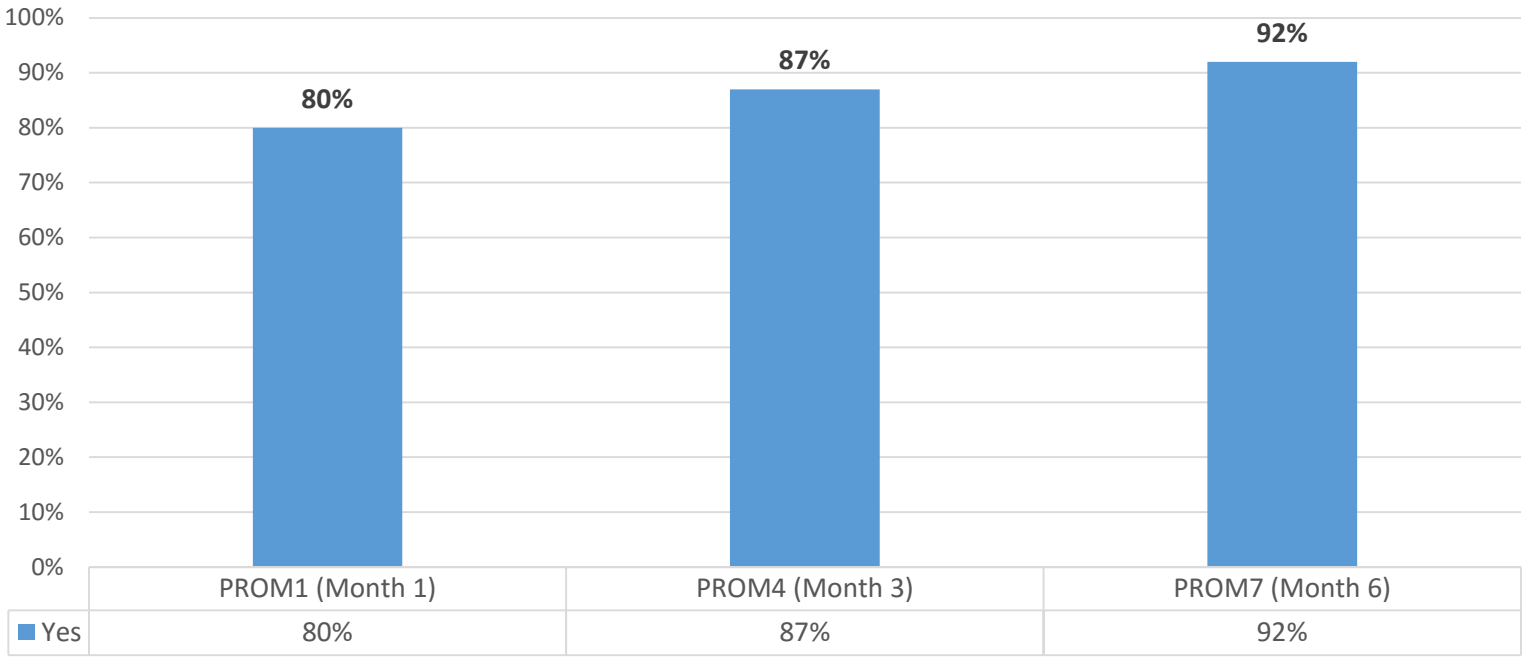
Did you have any problems completing the surveys because of technical issues?



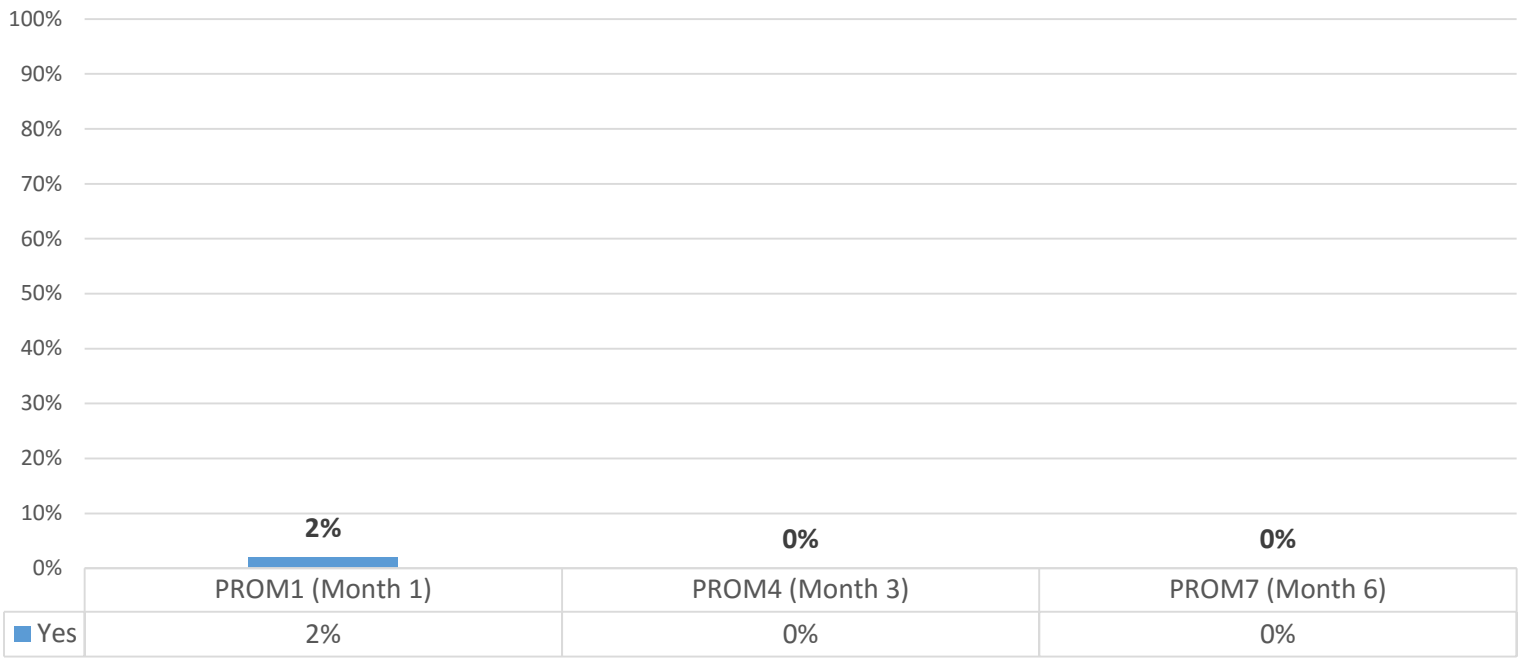
Did you have any other issues completing the online surveys?



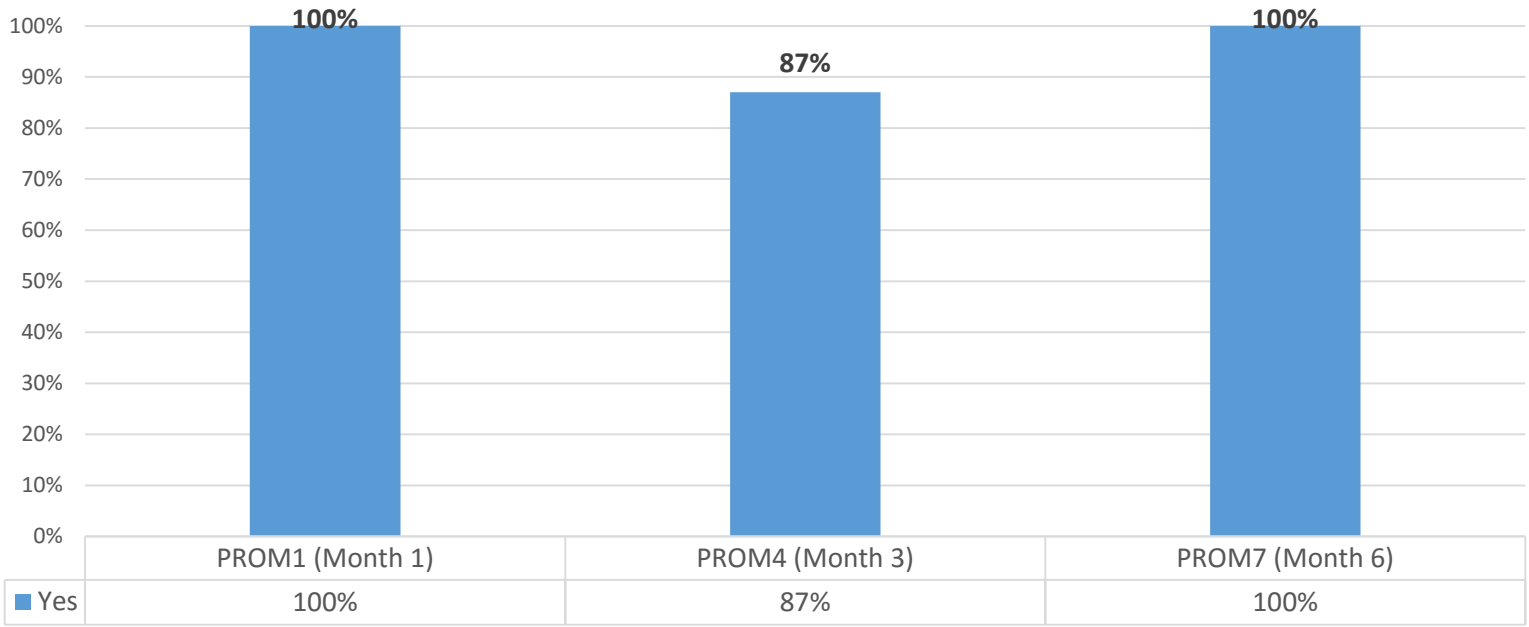
Did you receive your surveys as expected (i.e. an email every month)?



Did you find the online surveys too time consuming?

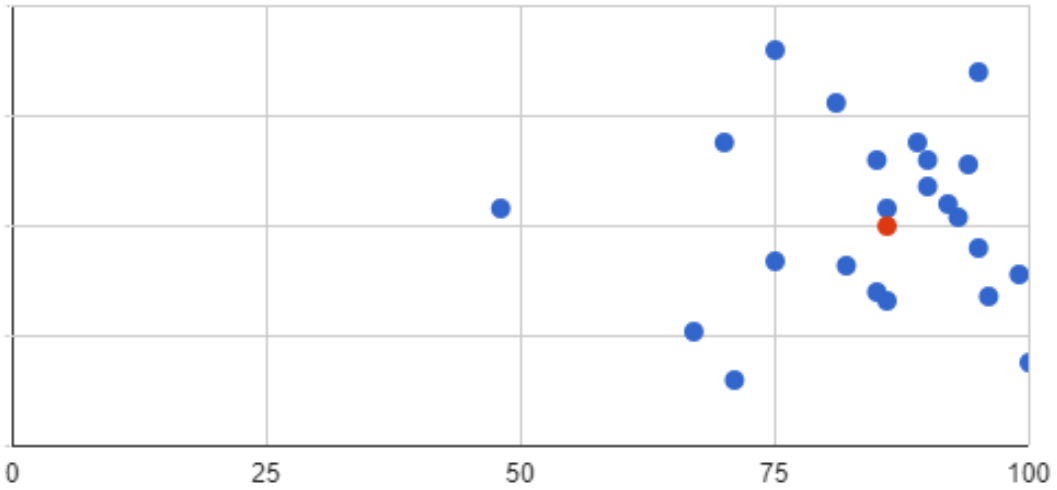


Do you think a £10 voucher is reasonable for the time taken to complete the surveys?

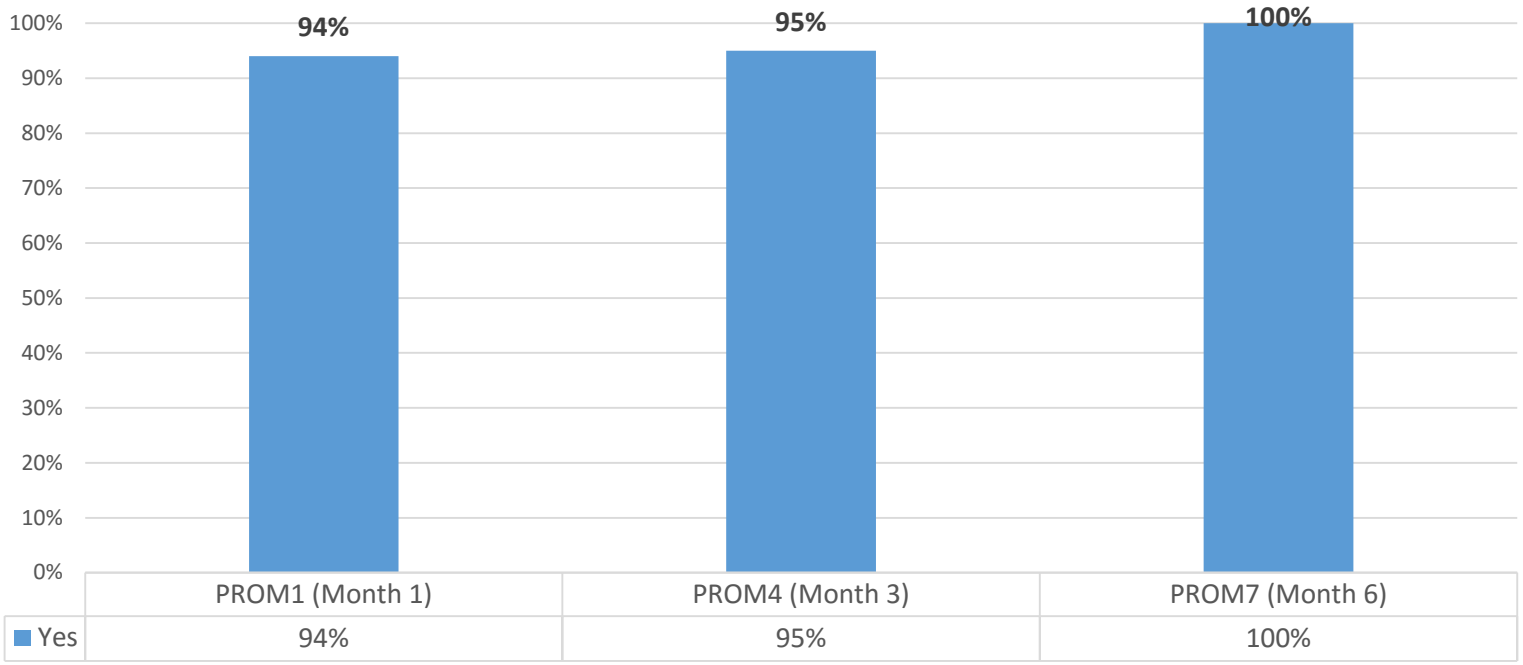


On a scale of 0 - 100, how do you rate your experience with the PROMiSe online study?

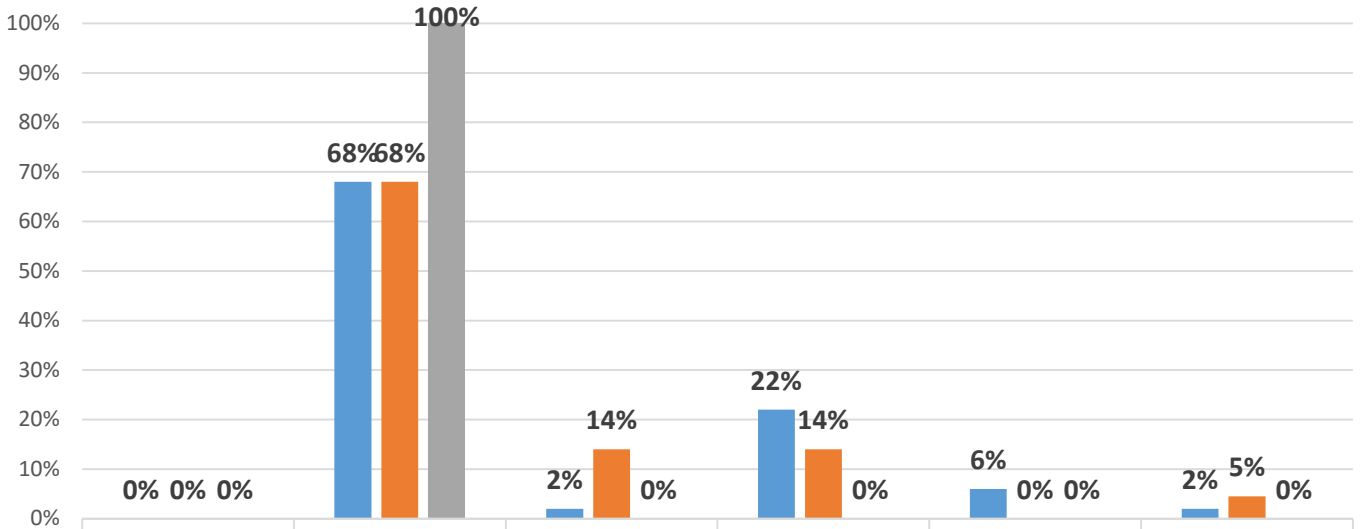
Lowest values: 48, 67, 70, 71, 75
Highest values: 95, 95, 96, 99, 100



If you were receiving treatment in hospital or from your GP, would you agree to take part in a study that used online consent & surveys (like the PROMiSe study) to help doctors assess your response to treatment?

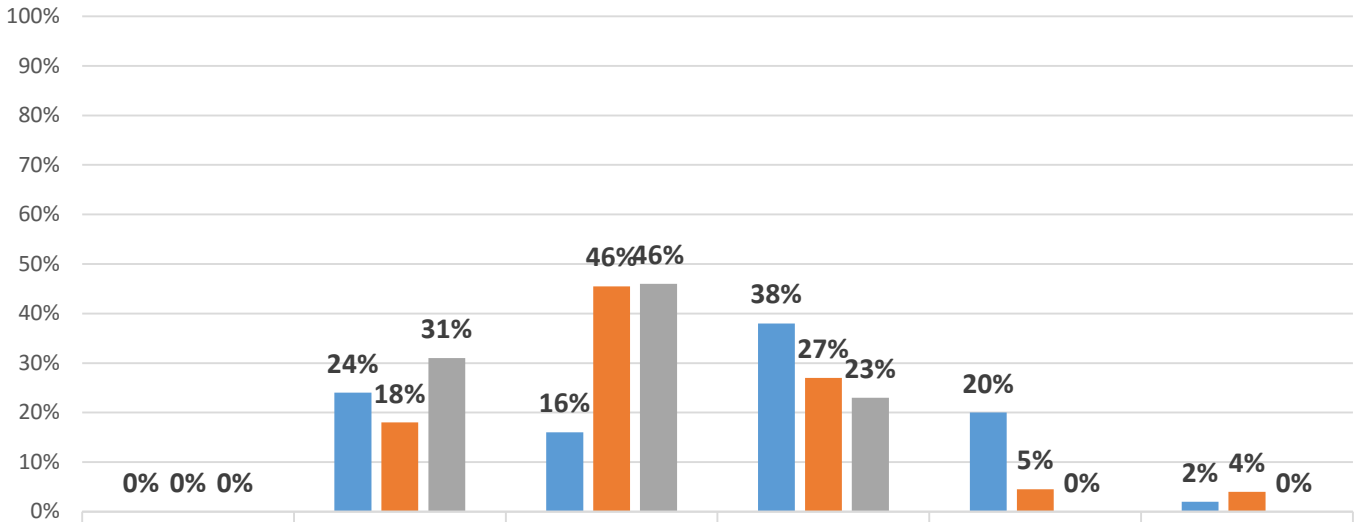


Preferred frequency of questionnaires 1 Year Study



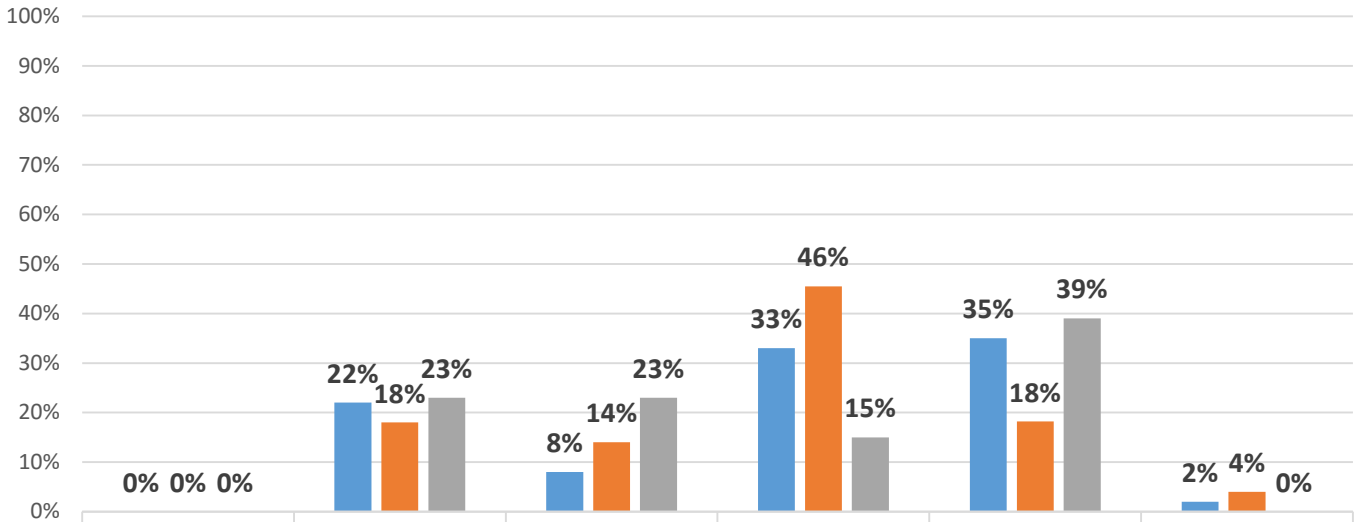
	Never	Once a month	Every 2 months	Every 3 months	Every 6 months	Annually
PROM1 (Month 1)	0%	68%	2%	22%	6%	2%
PROM4 (Month 3)	0%	68%	14%	14%	0%	5%
PROM7 (Month 6)	0%	100%	0%	0%	0%	0%

3 year study



	Never	Once a month	Every 2 months	Every 3 months	Every 6 months	Annually
PROM1 (Month 1)	0%	24%	16%	38%	20%	2%
PROM4 (Month 3)	0%	18%	46%	27%	5%	4%
PROM7 (Month 6)	0%	31%	46%	23%	0%	0%

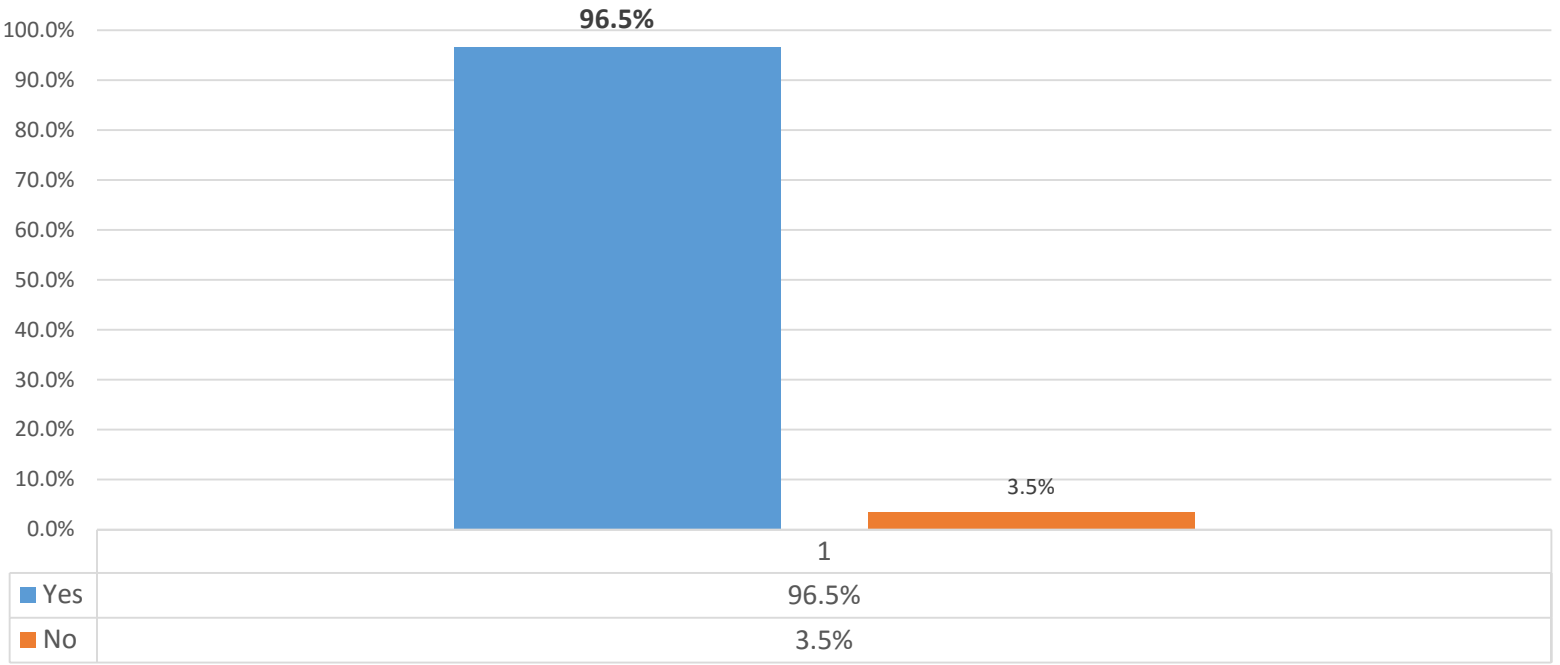
5 Year Study



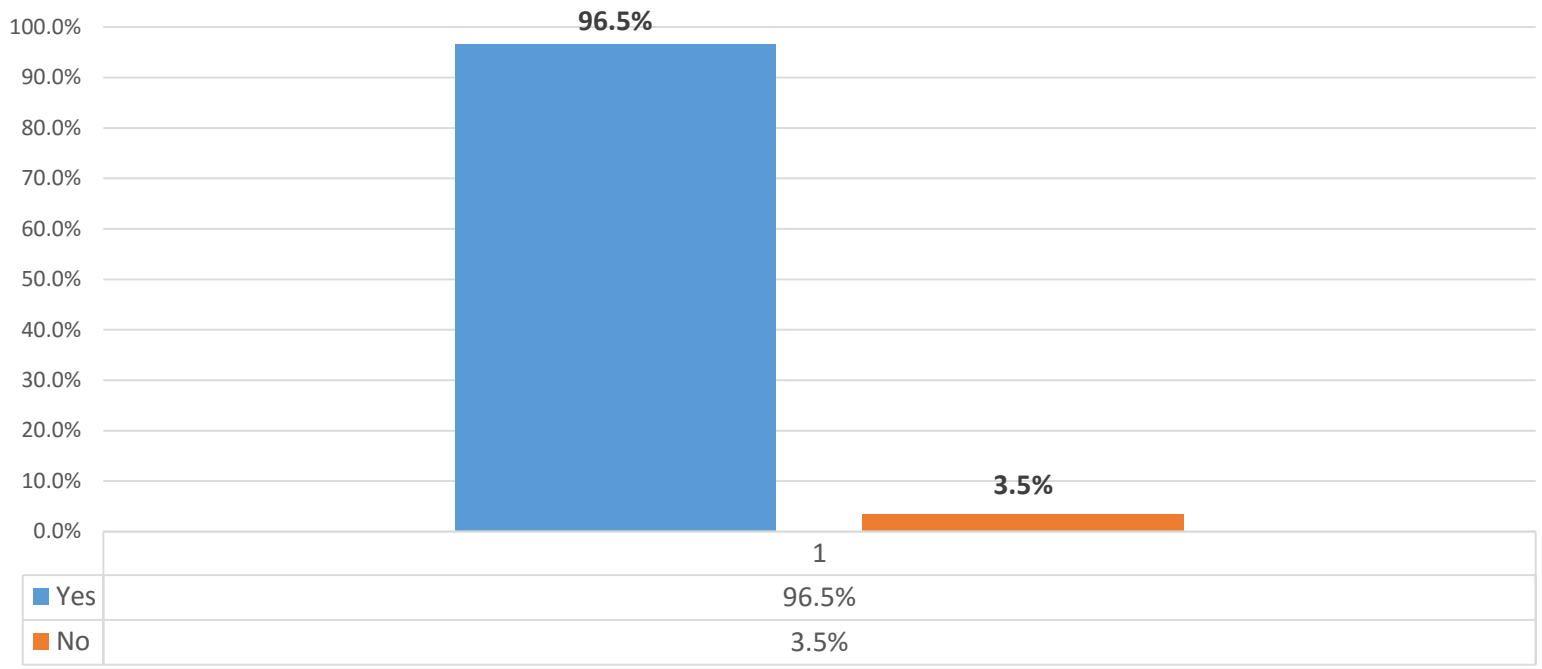
	Never	Once a month	Every 2 months	Every 3 months	Every 6 months	Annually
PROM1 (Month 1)	0%	22%	8%	33%	35%	2%
PROM4 (Month 3)	0%	18%	14%	46%	18%	4%
PROM7 (Month 6)	0%	23%	23%	15%	39%	0%

Accessing Medical Records

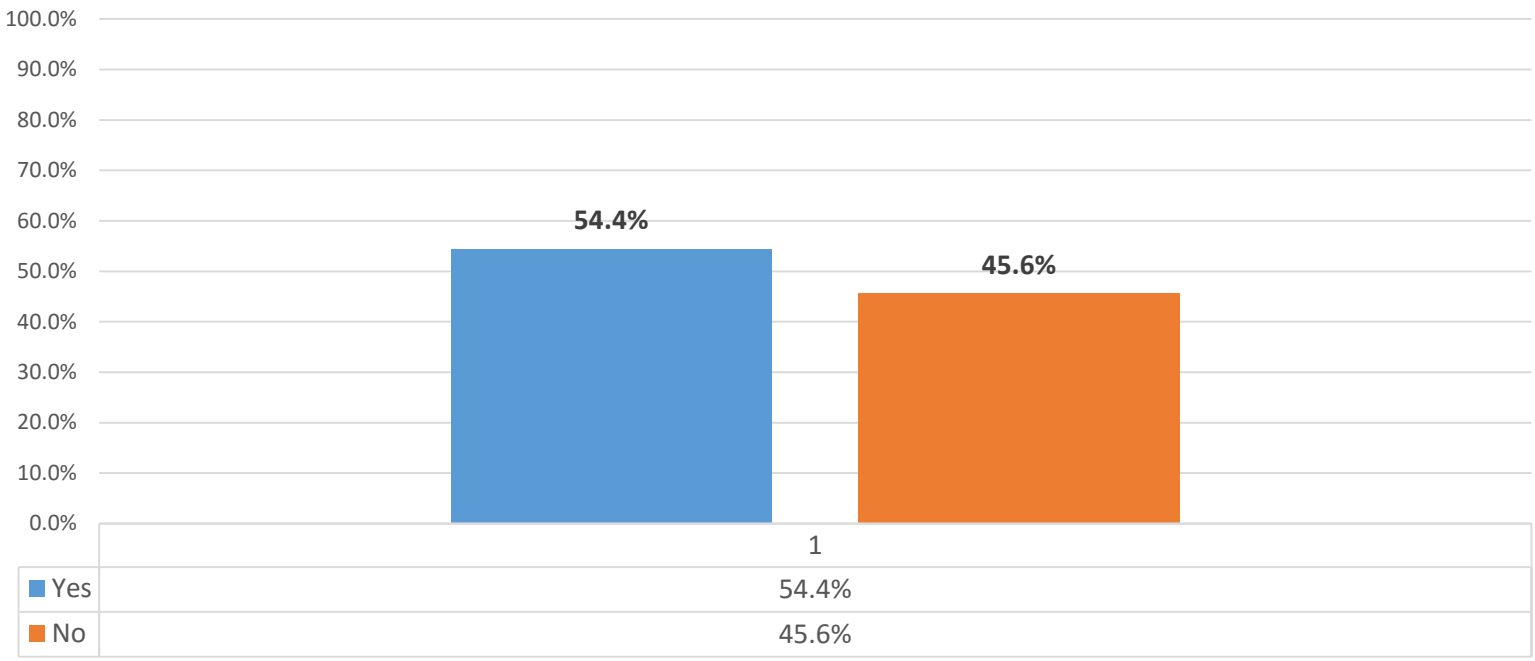
I agree it is important for researchers to access patient medical records for the purposes of research.



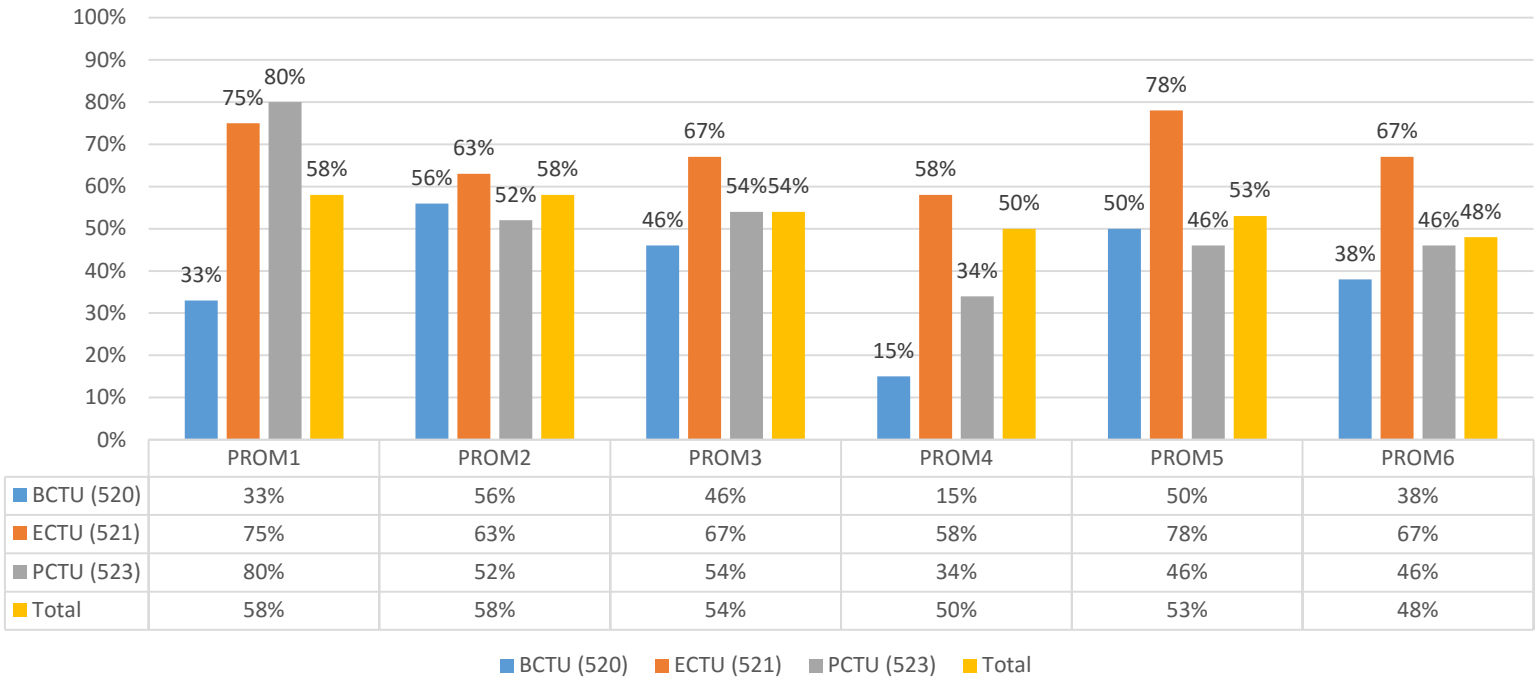
I would be willing to provide my medical record number (NHS number or CHI number) for research purposes.



I know my medical record number (NHS number or CHI number)



PROM1, PROM2, PROM3, PROM4, PROM5, PROM6 Response Rate



	PROM1	PROM2	PROM3	PROM4	PROM5	PROM6
BCTU (520)	33%	56%	46%	15%	50%	38%
ECTU (521)	75%	63%	67%	58%	78%	67%
PCTU (523)	80%	52%	54%	34%	46%	46%
Total	58%	58%	54%	50%	53%	48%

Thank you for listening. Any questions?