KADOORIE
OXFORD TRAUMA & EMERGENCY CARE | NDORMS

UNIVERSITY OF OXFORD

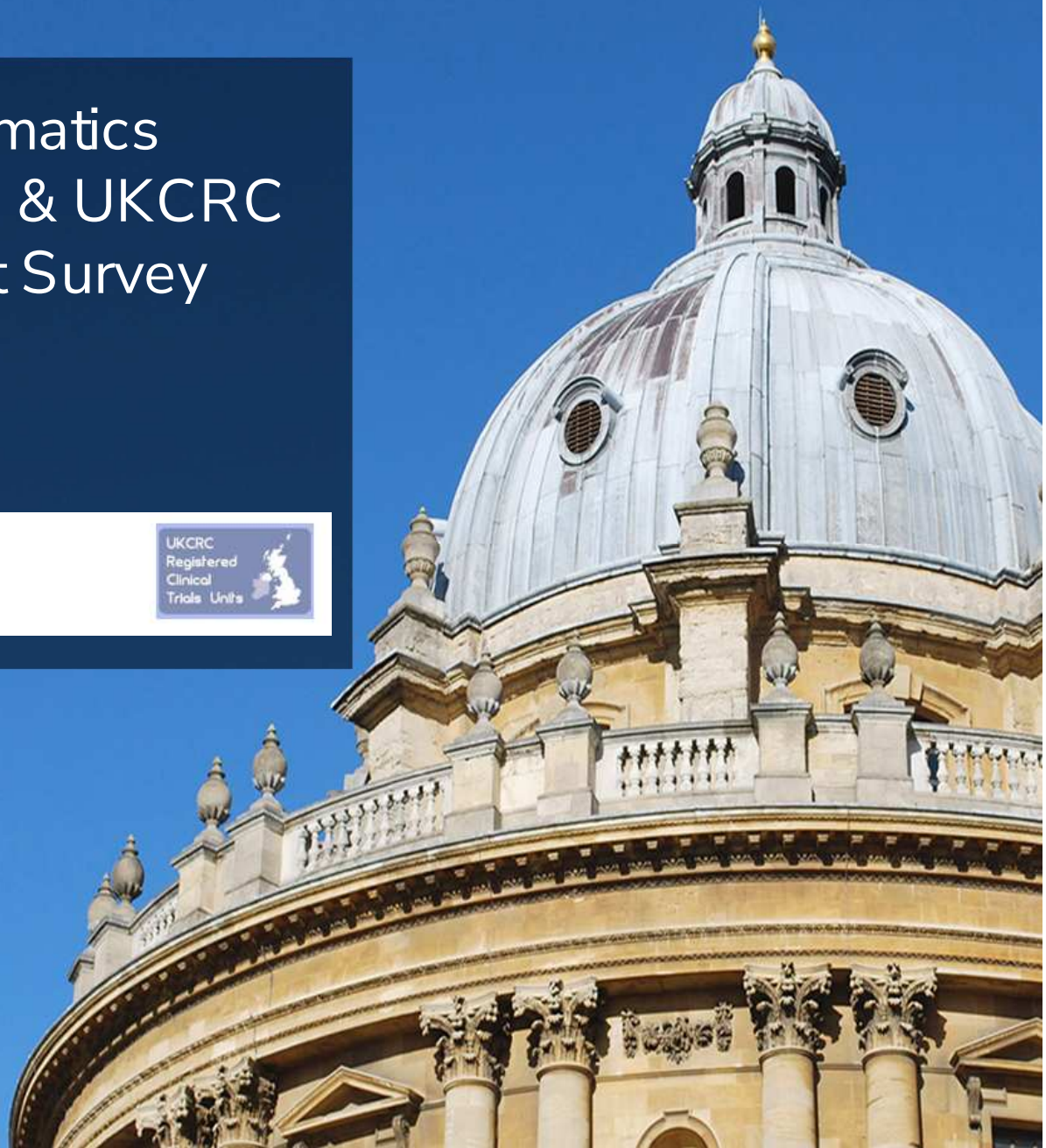
Joint TMRP Health Informatics Working Group, UKTMN & UKCRC CTU Network e-Consent Survey

The Highlights

Trials Methodology TMRP Research Partnership

UKTMN

UKCRC Registered Clinical Trials Units



Survey Steering Committee

The study steering committee comprises:

- TMRP HI WG:
  - Matt Sydes (UCL)
  - Amanda Farrin (Leeds)
  - Duncan Appelbe (Oxford)
  - Carrol Gamble (Liverpool)
- TMRP:
  - Paula Williamson (Liverpool)
- UKTMN:
  - Eleanor Mitchell (Nottingham)
- UKCRC
  - Helen Evans (Leeds)
  - Sharon Love (UCL)
  - Lucy Culliford (Bristol)
  - Katie Gillies (Aberdeen)
  - Kerry Hood (Cardiff)

With the survey being developed by DA, AF, MS, EM, SL & Judith Bliss (ICR).

Background

- Definition of eConsent (MHRA):

  "The use of any electronic media (such as text, graphics, audio, video, podcasts or websites) to convey information related to the study and to seek and/or document informed consent via an electronic device such as a smartphone, tablet or computer"

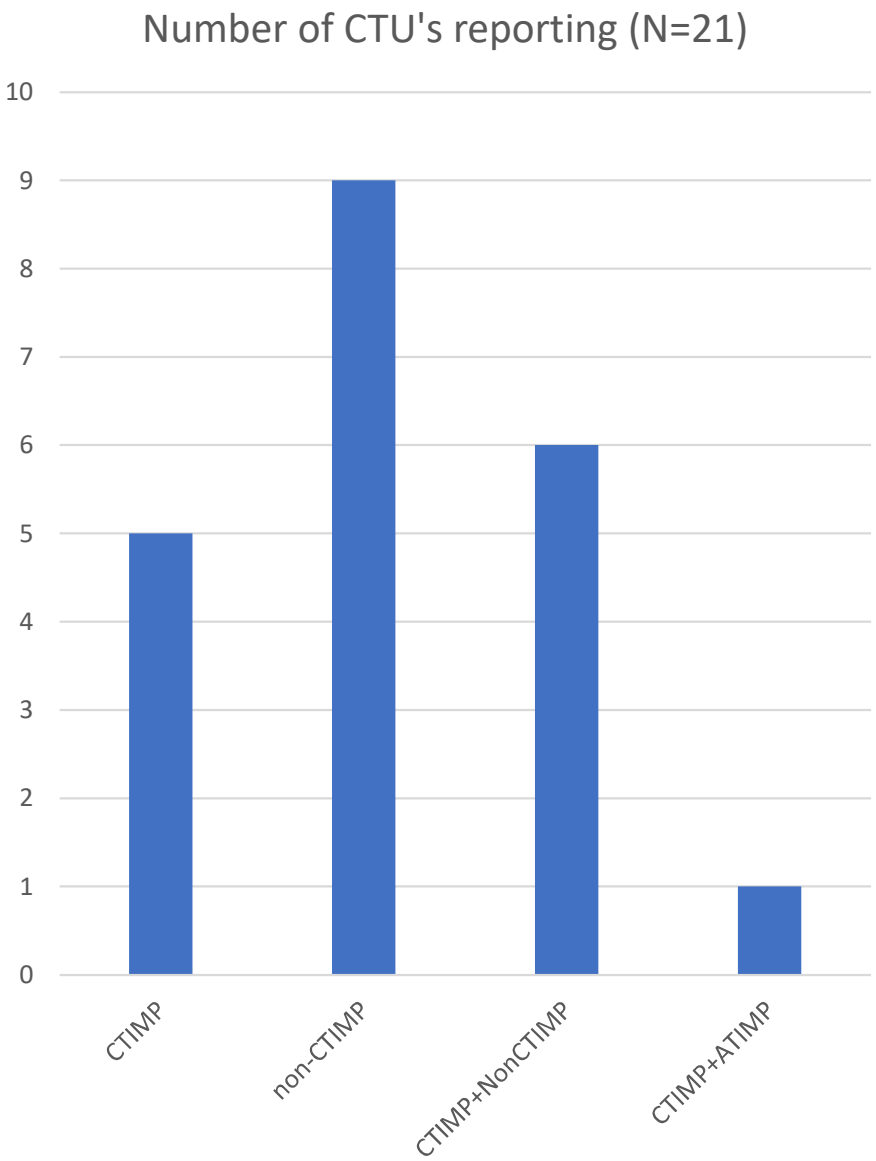
- Survey opened 27Apr2021 and closed 14Jul2021

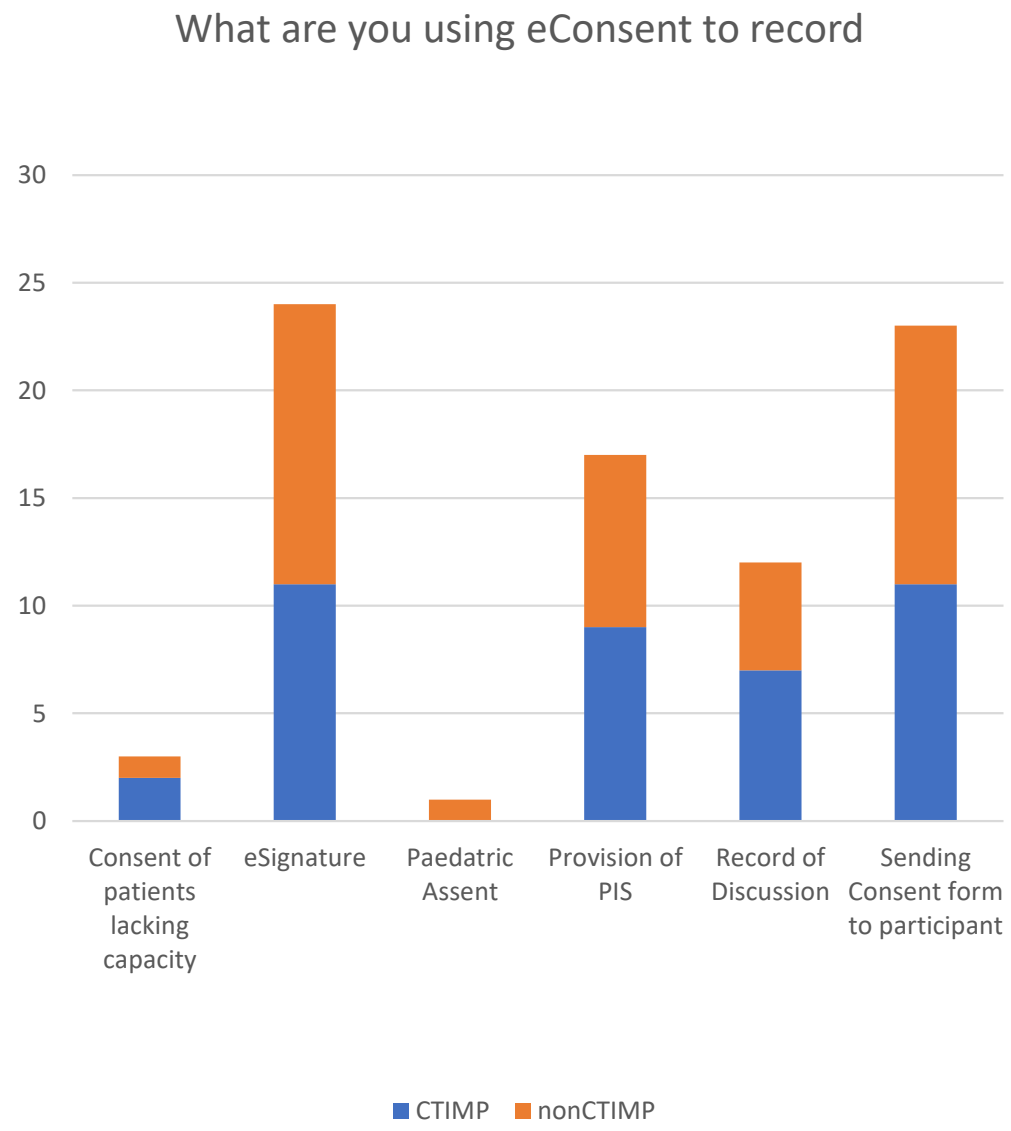
- The Survey asked
  - CTU level questions around plans, preparations and guidance used
  - CTU level questions around processes
  - CTU level Information Systems approaches/issues/validation/solutions
  - CTU level QA queries
  - If CTU's could provide data from example CTIMP/ATIMP/non-CTIMP studies with
    - Trial specific questions on implementation/operational aspects
  - At each level asked if there were outstanding questions/what did you wish you had known

Responses

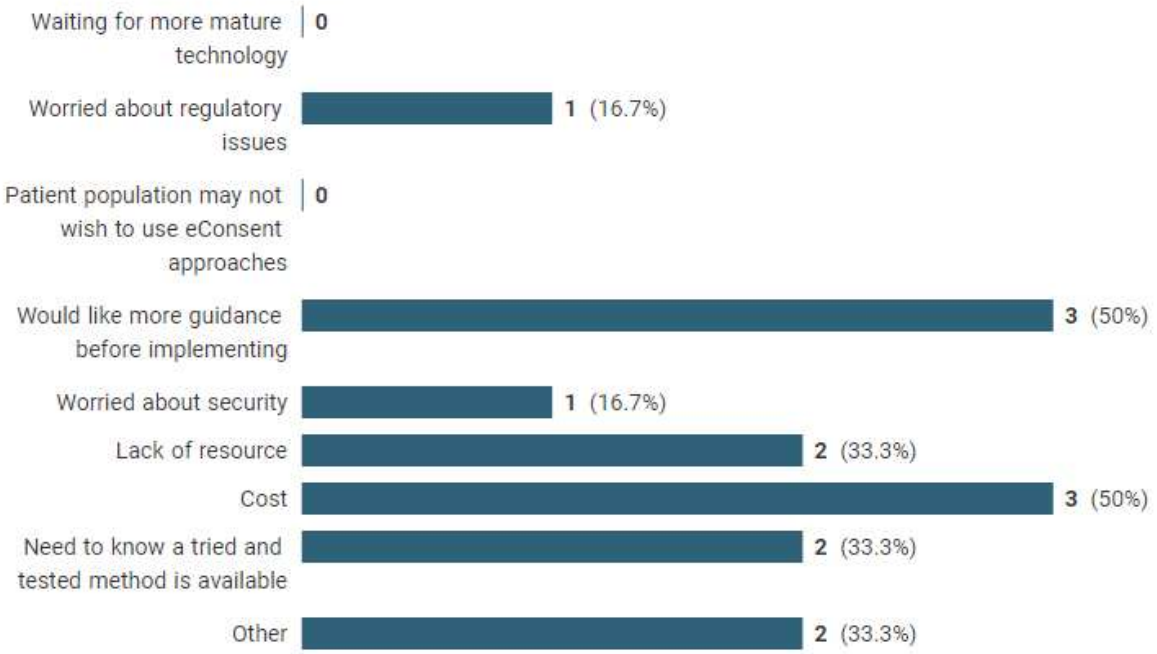
- Thirty-four (64%) of 53 UKCRC CTU's completed the survey.
- Of the 34 responses received, 21 CTUs (62%) stated that they were currently using any form of eConsent in any trials or were currently integrating eConsent into an existing trial
- Of the 13 CTU's who responded that they were not using eConsent, seven (54%) stated that they planned to implement eConsent in the next 6-12 months

What Studies were reported on ….?





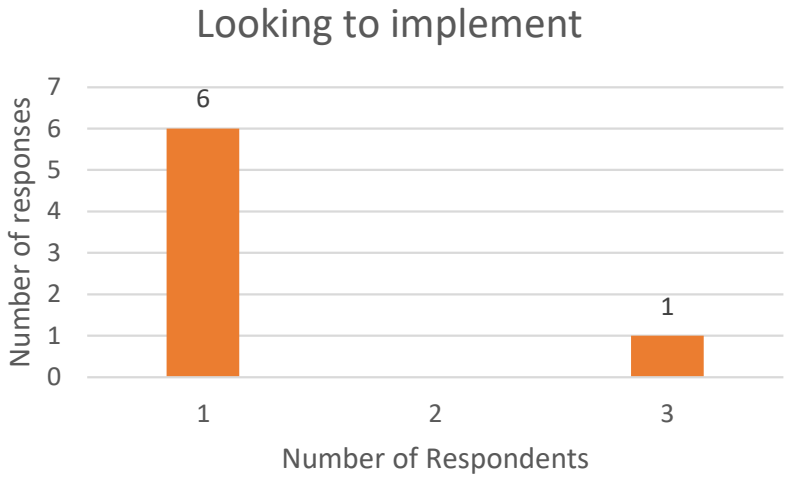
Reasons why CTU's are not implementing eConsent in the next 6-12 months



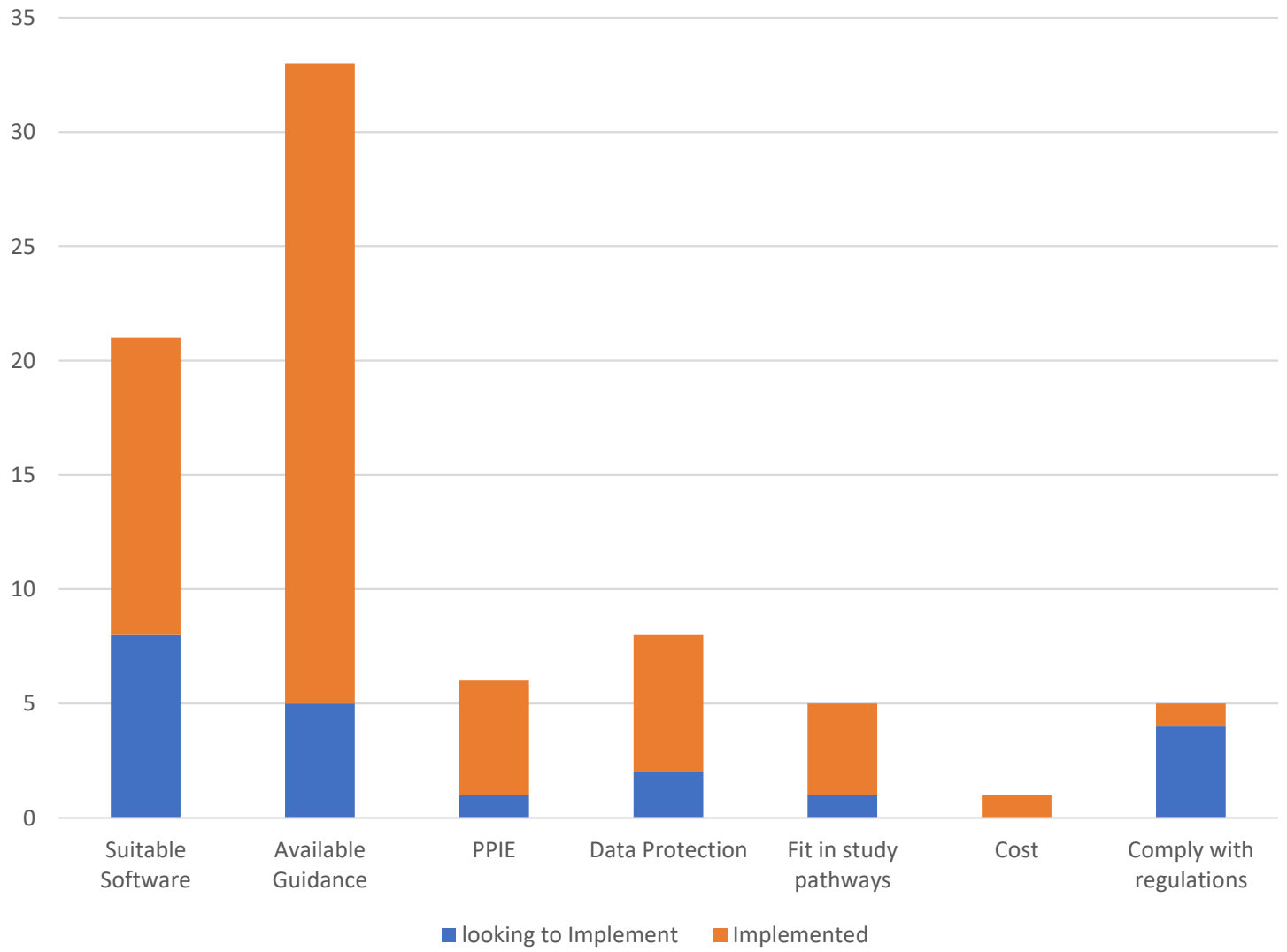
- Six CTU's
- More than one answer allowed

These themes are repeated in the questions attendees have posed

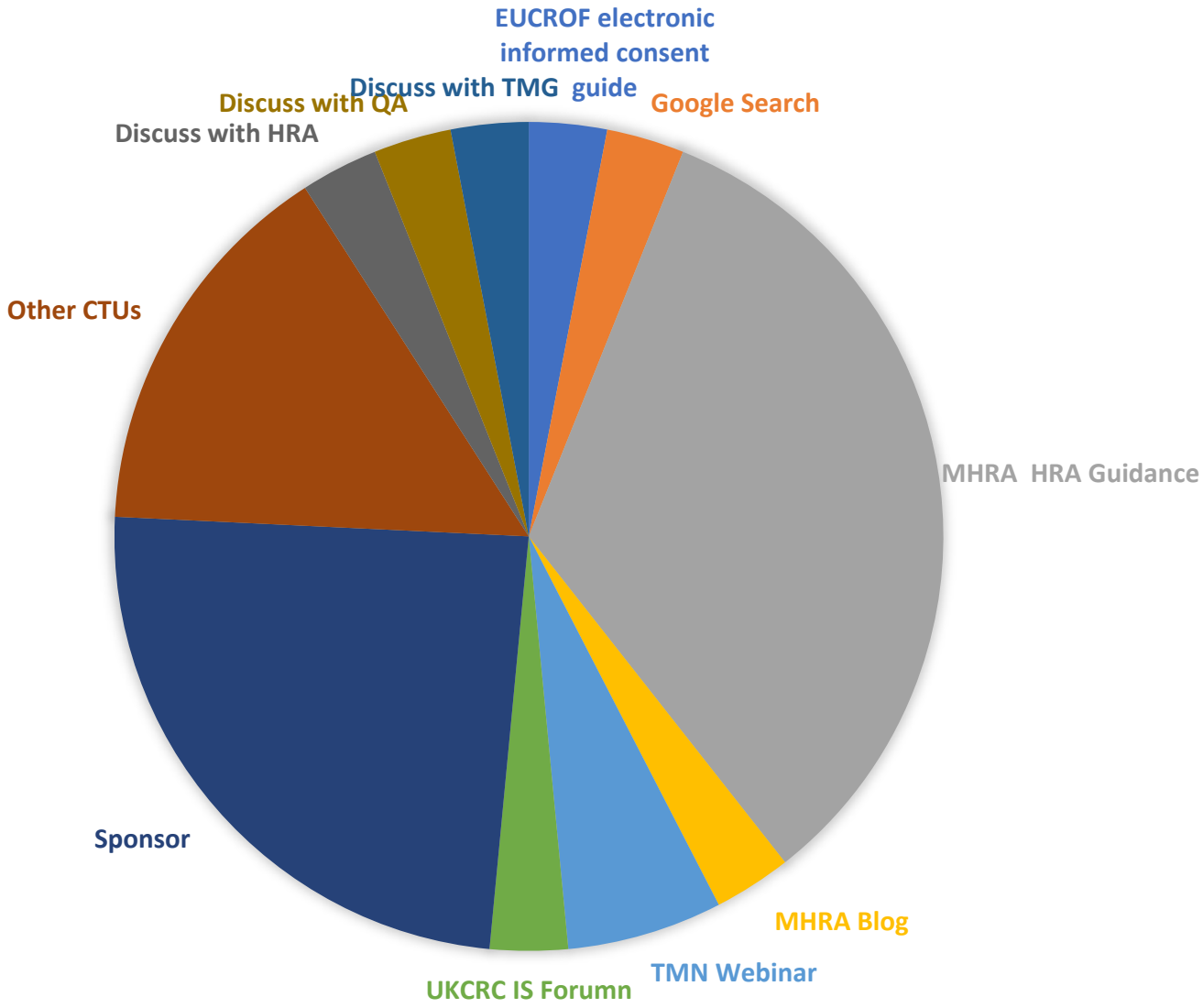
- Looking to purchase a system
- No suitable trials in this period



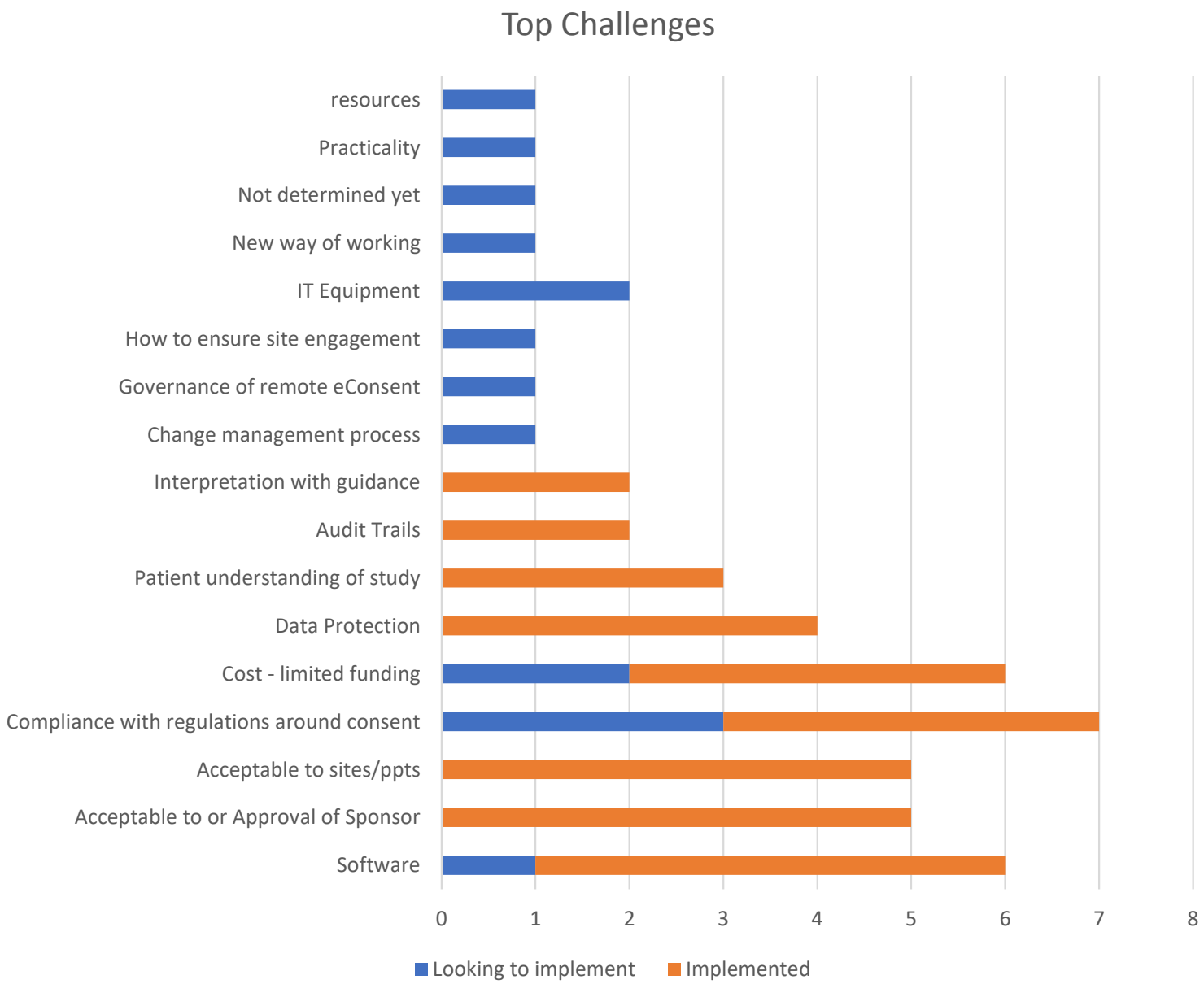
Preparatory Work from CTU's looking to implement or have implemented eConsent

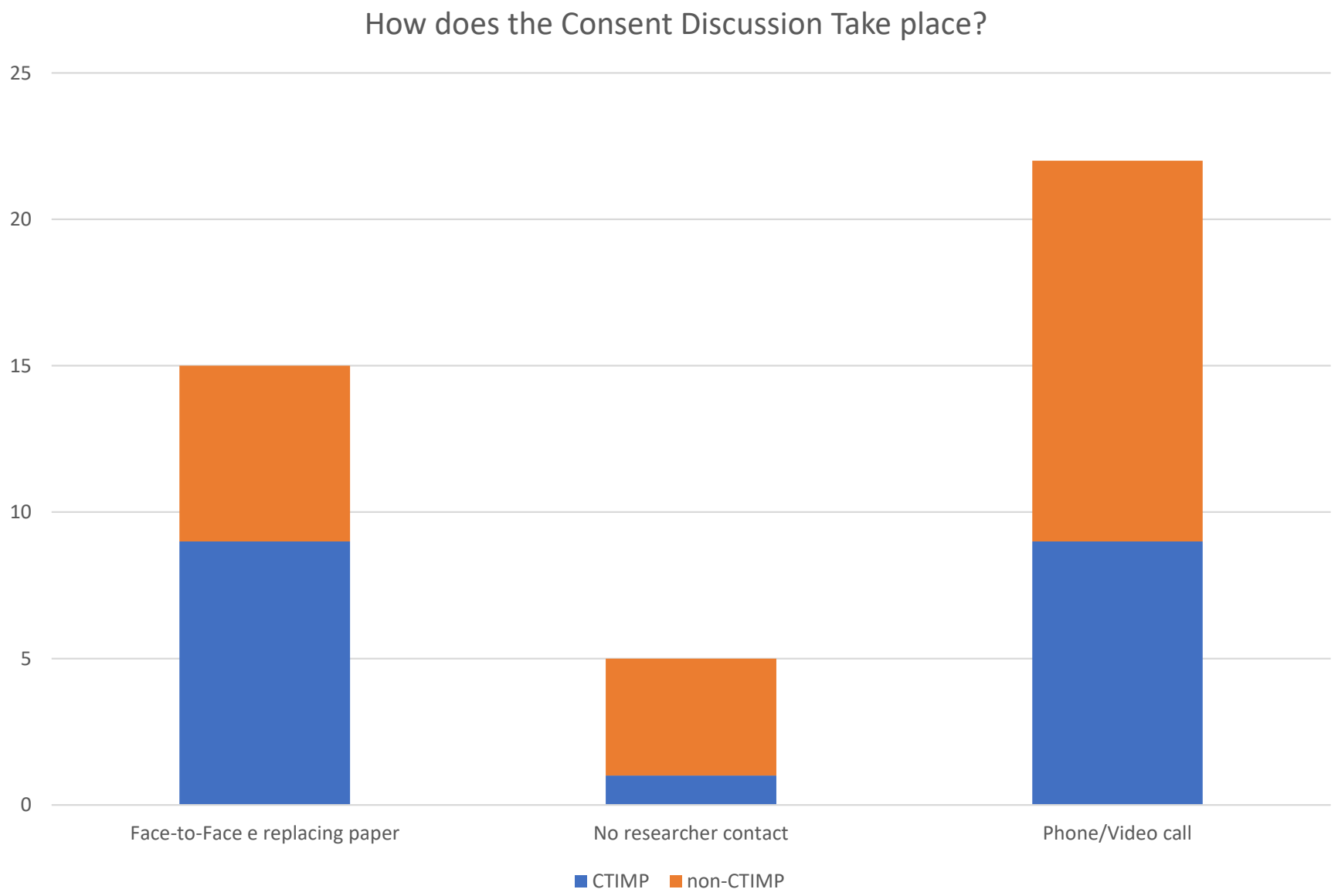


Guidance Referenced



Challenges ….


Top Challenges
resources
Practicality
Not determined yet
New way of working
IT Equipment
How to ensure site engagement
Governance of remote eConsent
Change management process
Interpretation with guidance
Audit Trails
Patient understanding of study
Data Protection
Cost - limited funding
Compliance with regulations around consent
Acceptable to sites/ppts
Acceptable to or Approval of Sponsor
Software
0
1
2
3
4
5
6
7
8
Looking to implement
Implemented

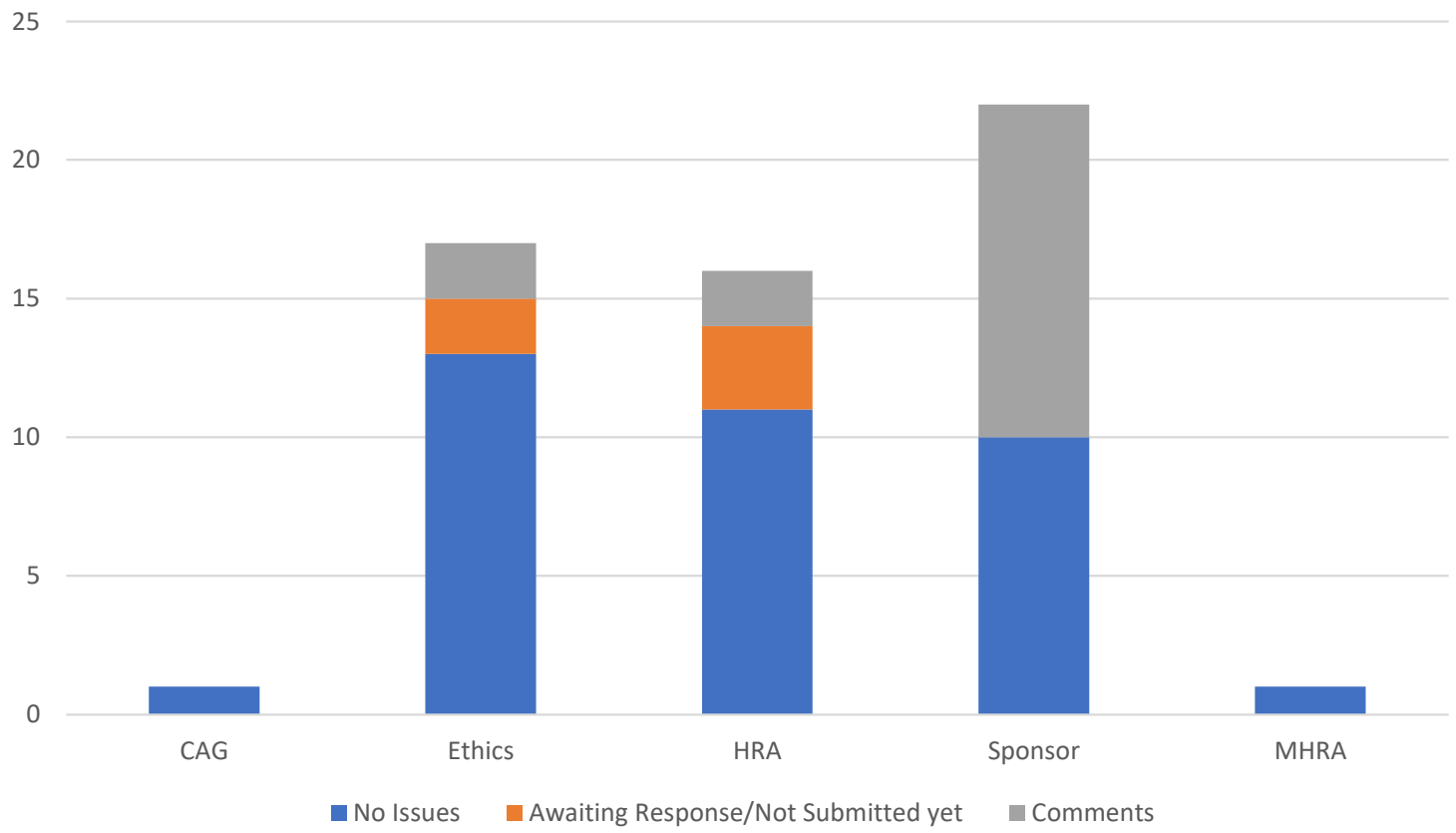

How does the Consent Discussion Take place?
25
20
15
10
5
0
Face-to-Face e replacing paper
No researcher contact
Phone/Video call
CTIMP
non-CTIMP

Identity Checks

The identity of the participant was confirmed in several different ways (more than one option could be specified) ranging from direct contact (either in clinic [N=17] or phone/video call [N=20]) to sending the participant an electronic link to their phone/eMail (N=21).

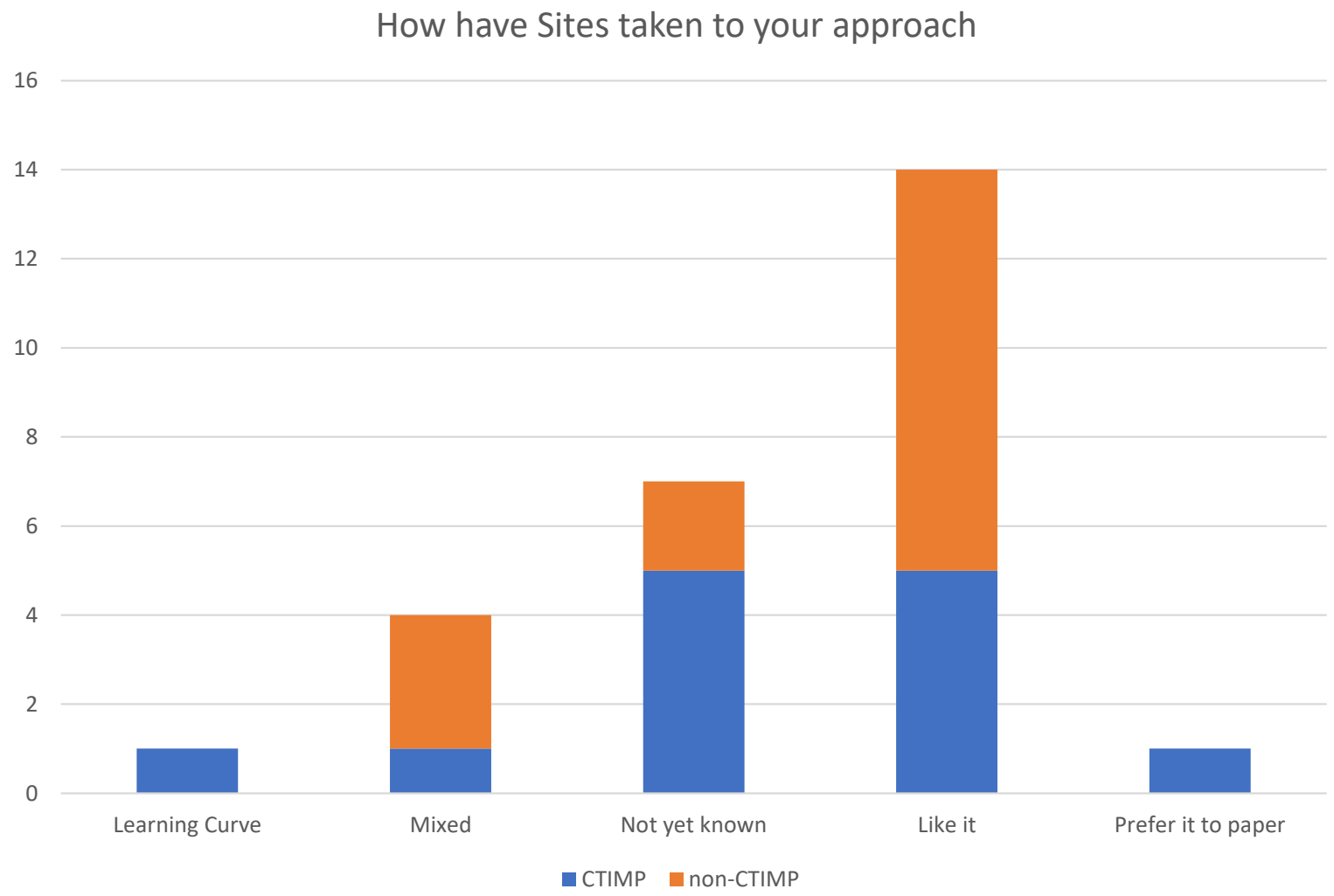
Given that the use of electronic systems has the potential for automating checks between delegation logs and eConsent forms, CTU's were asked how they confirmed that researchers taking consent were on the delegation log. Responses here (multiple allowed) ranged from electronic check between systems (N=5), enabled based on role when they log in (N=10) to manual checks (N=18).

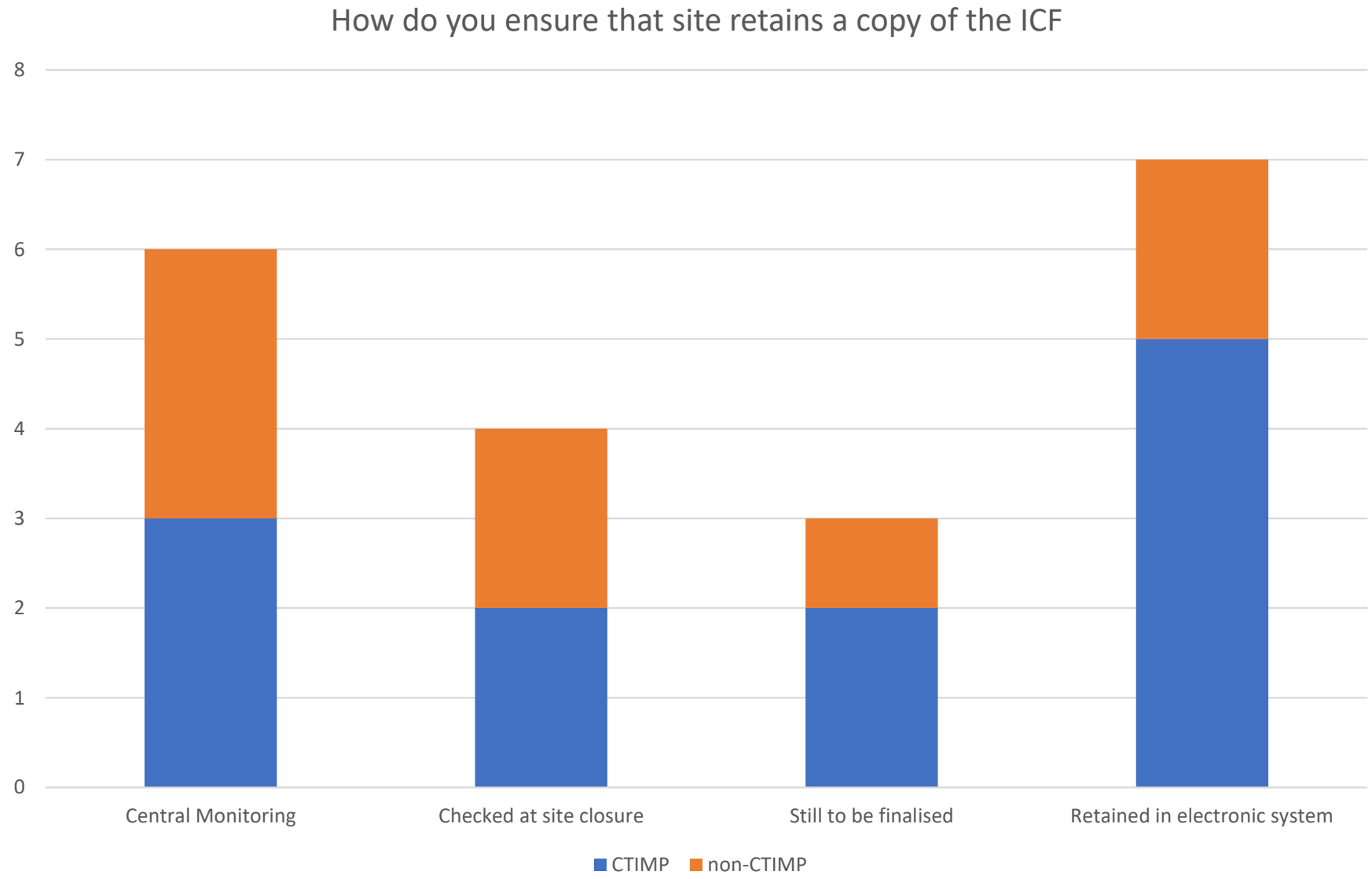
Feedback from Approval Bodies



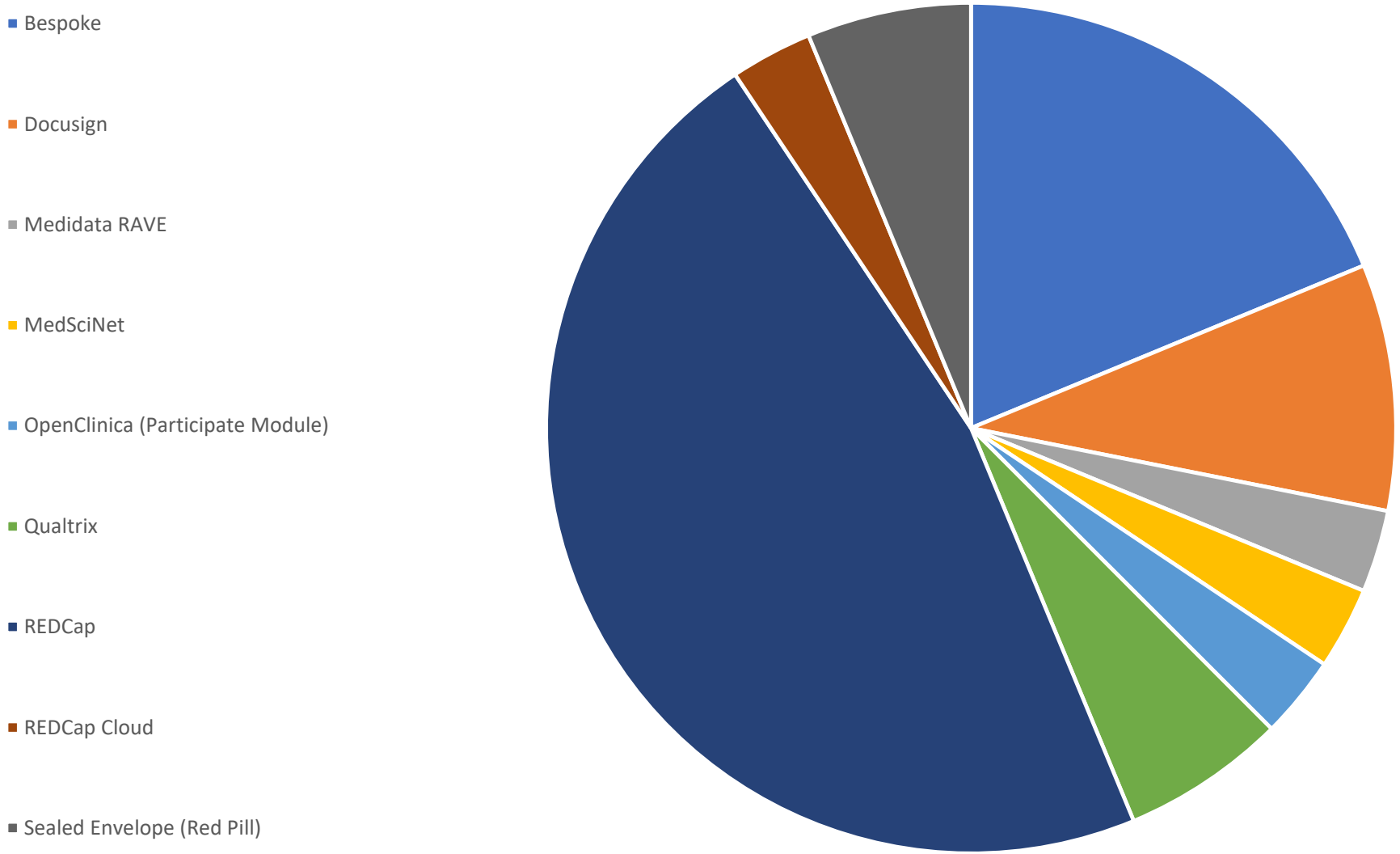
At the time of the survey the MHRA had not inspected any responders using eConsent

Sites Response to implementation




How do you ensure that site retains a copy of the ICF
8
7
6
5
4
3
2
1
0
Central Monitoring
Checked at site closure
Still to be finalised
Retained in electronic system
CTIMP
non-CTIMP

Systems utilised to provide eConsent



Security of data

The security of consent form data (including PID) is in the main based on the security of the server hosting the application and roles within the eConsent software/server. Only five CTU's stated that the consent data was encrypted at rest

Those studies that send the consent form to the participant were further asked if they encrypt the consent form and if so, how they provide the key to the recipient. The responses provided were:

- No – not encrypted (N=18)
- N/A (N=3)
- Yes (N=2)
  - System generated code given to participant by site
  - E-Mail with link
- Downloaded direct (N=1)

What else would we still like to know?

- Better Guidance (CTU Level, QA, IS, TM)
- Practical Examples (CTU Level, QA, IS, TM) ← Next two speakers/other attendees
- Expectations from Regulators
- What other CTUs have done ← Opportunities today
- Best mechanism for transferring Consent forms to participant

Thanks to all of those CTUs that responded to the survey.

Any questions please contact me at:
duncan.appelbe@ndorms.ox.ac.uk

eConsent in the VROOM Trial

Presented by
Lucy Cureton
Clinical Trials Manager
OCTRU (Oxford Clinical Trials Research Unit)

eConsent in the VROOM study

- The Trial: VROOM: vaccine response on/off methotrexate: does temporarily suspending methotrexate treatment for two weeks enhance covid-19 vaccine response? A Randomised Controlled Trial. Urgent COVID study!
- Why eConsent? A move towards paperless studies within OCTRU. Protocol states that paper consent can be used if needed – so far not happened.
- How? Consent taken electronically at face-to-face baseline clinic visit at participating centre. Sites provided with an iPad. VROOM ethically approved paper consent form converted into a data matrix which is then programmed into REDCap database. Consists of radio buttons, optional statements (Y/N), space for electronic signatures, date fields and validation to ensure no fields missed/completed incorrectly.

Once completed, a PDF version of the consent form is automatically emailed to the participant and becomes available in REDCap for sites to download for filing in site file and medical notes.

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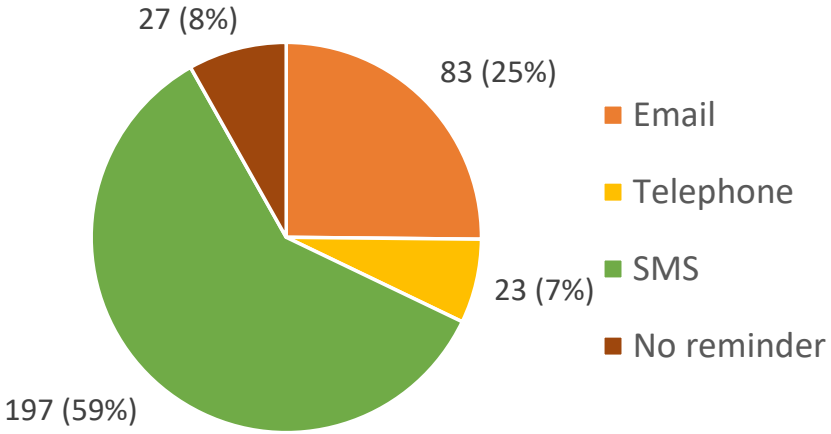
Nuances to eConsent system

- So many nuances! We refer to the VROOM database as having a lot of ‘bells and whistles’
- Part of VROOM is asking participants how they would like to be contacted with reminder messages and questionnaire - email/postal/telephone. These options have been included on the consent form and these fields ‘trigger’ certain actions e.g. if the participant selects that they wish to receive a text message to remind them what intervention they have been allocated to, the study database systems are programmed to send SMS text messages to the participant at the relevant time points.
- ‘Flow’ of forms: in REDCap’s survey mode, once a form is completed, the next form in the process automatically opens. Ensures no forms or missed or completed at the wrong time.

Baseline part 1 ➔ consent form ➔ baseline part 2 ➔contact details ➔ participant questionnaire

Nuances to eConsent system



Ability to run reports on consent form data, for example, to see patients' contact preferences for receiving reminders about the VROOM study. Can't do that with paper!
REDCap reports and OCTRU's Study Information Management System (SIMS) make it easy to pull real-time data in this way.

- Some fields in the eConsent are 'piped' through to other CRFs. Date of consent is used as validation on other date entries in later forms, e.g. date of blood sample cannot be before date of consent.
- Pre-populated read-only fields for ease of completion and QA: date set for today's date, participating site and participant ID number.
- Using form render skip logic, other CRFs can't be started until consent successfully completed.

Challenges with implementing or managing eConsent

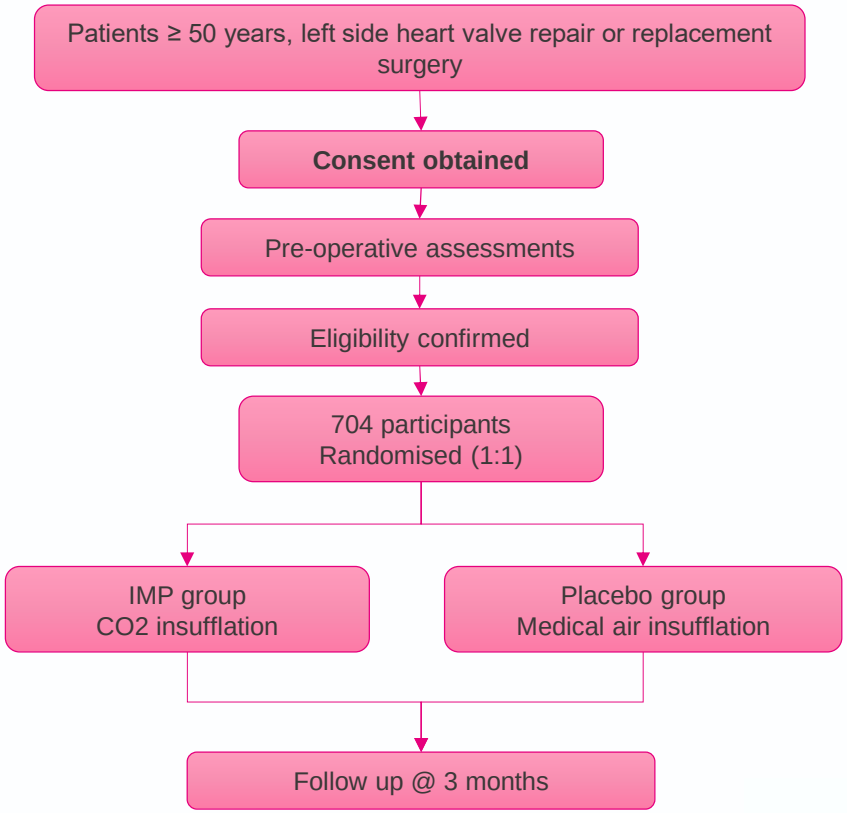
- Linked CRFs, a mistake in one CRF can lead to it being cascaded to the CRFs it is linked to.
- Front loaded process; large amount of work required up front in building and testing the database, but saves time across whole of trial as many systems are automated.
- Process to send consent forms to participants' email addresses, if entered incorrectly email bounces back and we have to send the consent form manually.
- Every time there is an amendment to the consent form, updating the form on REDCap, re-testing, and releasing is quite an involved process.

Quote from VROOM study nurse: Using the electronic consent has been really easy to use. The best part about it is it can be accessed from any iPad or computer and you don't have to worry about which version the consent form is as it's managed from CTU end. Patients have found it easy to use too and the electronic signature is always a talking point. I really think this should be used in all the studies I am involved in.

Bristol Trials Centre case study: including remote e-consent in the CO2 study

Rachel Todd
Senior Research Associate in Clinical Trials Management

Carbon Dioxide Insufflation and Brain Protection During Open Heart Surgery: A Randomised Controlled Trial



Design: Multicentre, parallel two-group placebo-controlled blinded Randomised Controlled Trial

Study population: Patients aged 50 years and above undergoing left side heart valve repair or replacement

Aim: To evaluate the efficacy and safety of CDI in patients undergoing planned open left side heart valve surgery.

IMP: Carbon dioxide insufflation

Placebo: Medical air insufflation

Primary outcome: Acute ischemic brain injury within 10 days post surgery

NHS University Hospitals Bristol and Weston NHS Foundation Trust
FUNDED BY NIHR National Institute for Health Research
BRISTOL TRIALS CENTRE

Remote e-consent process

Call the patient to discuss the study and answer any questions they have.

Ask patient for their email address

Enters patient's email address into REDCap e-consent module.

Patient receives email with link to the electronic form

Each consent item discussed with the patient, patient initials and the electronically signs the form

Electronic consent form reviewed and electronically signs by person taking consent to confirm they obtained consent.

Patient receives email with link to download PDF of the consent signed by both parties, their records. Clinician/Research Nurse prints PDF of consent and files.

Reduced admin and paper usage

Pandemic induced technical competence

Dedicated 'space' and time for consent

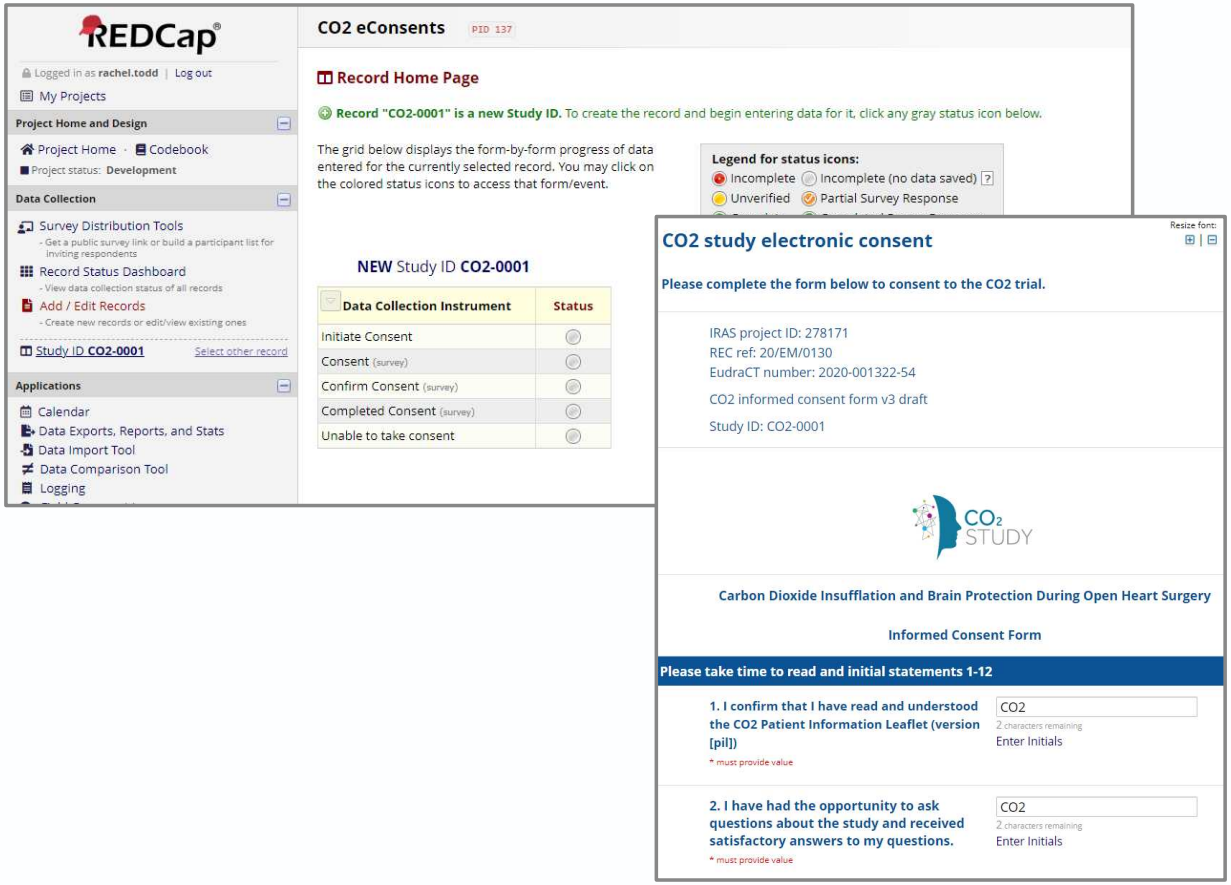
Compliments other consent methods

'Easier for patient'

BRISTOL TRIALS CENTRE

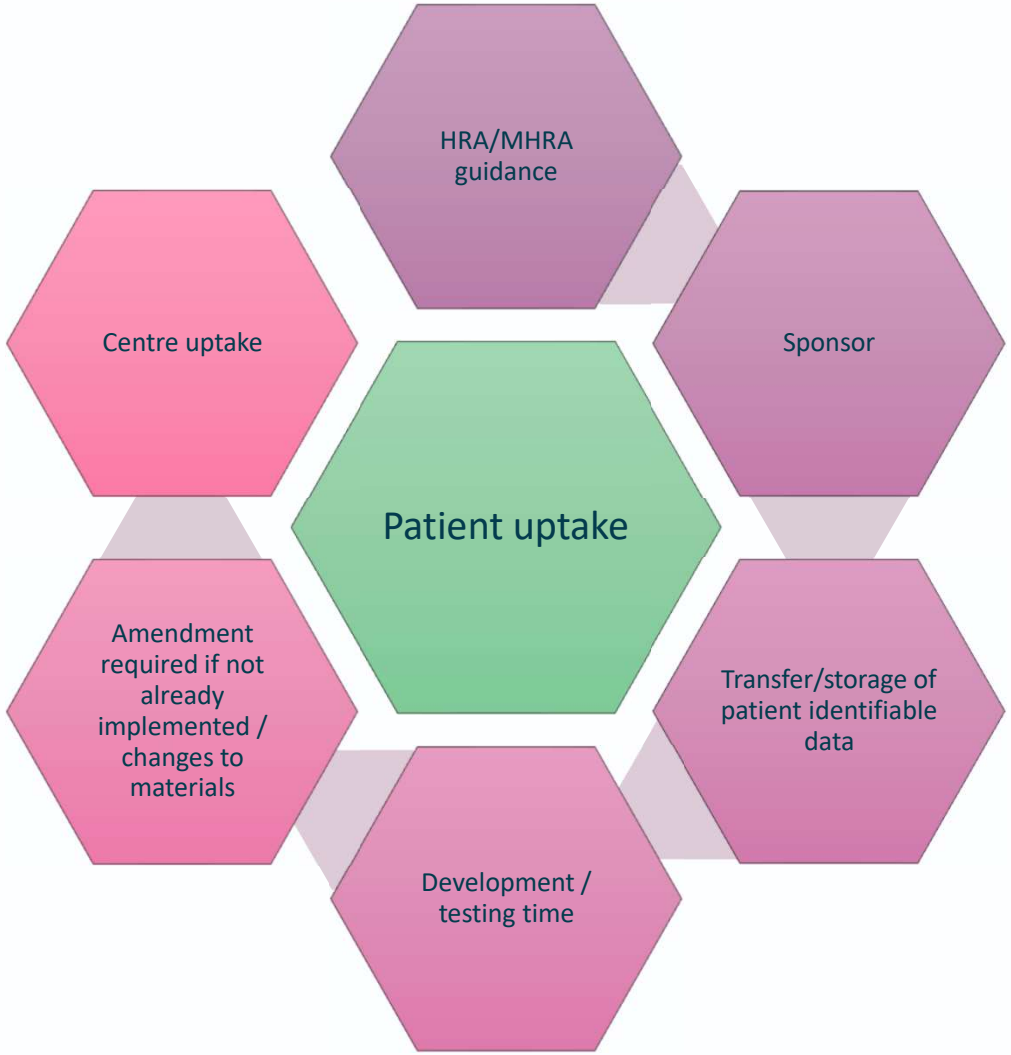
Using an ‘off the shelf’ system

- REDCap e-consent module
- Modified to mirror paper consent process
- Fail safes added
- Very little remains the same
- Bespoke may have saved time



BRISTOL TRIALS CENTRE

Challenges implementing



BRISTOL TRIALS CENTRE