

Please see below for a link to the webinar recording for the Trials Methodology Research Partnership:

Are electronic study management systems acceptable to participating sites?

Maddie Clout and Hana Tabusa, University of Bristol

22 July 2020

The slides are also available below.

For any queries, please contact uktmn@nottingham.ac.uk

<https://www.youtube.com/watch?v=iLoEbXhxj98&feature=youtu.be>

Are Electronic Study Management Systems Acceptable to Participating Sites?

Maddie Clout & Hana Tabusa

Bristol Trials Centre, Clinical Trials and Evaluation Unit



REASONS FOR USING ELECTRONIC SYSTEMS



To manage multi-centre studies more efficiently



To reduce paper use in the study



To minimise storage requirements



To allow remote access

WORKING FROM HOME & COVID-19

- Limited access to paper files
- Electronic systems increase flexibility
- Documents can be accessed from anywhere
- The delegation log can be accessed and signed off from anywhere

DEMO OF THE STUDY MANAGEMENT SYSTEM



DELEGATION LOG



INVESTIGATOR
SITE FILE

SUNFLOWER TRIAL MANAGEMENT SYSTEM



LOG IN

Please enter your username and password.

ACCOUNT INFORMATION

Username:

Password:

Log In

[Register here](#)

[Forgotten password?](#)

Clinical Trials and Evaluation Unit
University of Bristol, Level 7, Bristol Royal Infirmary, Upper Maudlin Street, Bristol, BS2 8HW

SUNFLOWER TRIAL MANAGEMENT SYSTEM

CREATE A NEW ACCOUNT

Please enter the type of access you require

REQUESTED ACCESS

Role:

Please select role ▼

Centre:

- ▼

Previous

Next

DELEGATION LOG

Start Date

End Date

GMC/NMC (clinical staff only)

Tasks

Site staff tasks:

- 1. Maintaining local investigator site file
- 2. Screening/recruiting study subjects
- 3. Maintaining patient screening log
- 4. Confirming eligibility (inclusion/exclusion)
- 5. Obtaining informed consent
- 6. Randomising patients
- 7. Completing CRFs
- 8. Data entry
- 9. Resolving data queries
- 10. Notifying participant's GP
- 11. SSI completion (Scotland and N. Ireland only)
- 12. Preparing local documents
- 13. Obtaining local approvals
- 14. Maintaining site delegation log
- 15. Dealing with study amendments
- 16. Completing/reviewing SAE forms
- 17. Reporting of protocol deviations/breaches
- 18. Providing patients with questionnaires
- 19. Dealing with queries from patients
- 20. Sending patient information leaflets
- 21. Archiving study documentation
- 22. Approving changes to site delegation log (Principal Investigator only)

[Delegation Log](#)

Documents

[Contact Details](#)


[Database Role](#)

[Change Password](#)

DOCUMENTS TO BE UPLOADED

CV: [cloutmad Clout M Short CV 13062018.doc](#)

CV **13/06/2018**


Date: 

No file chosen

Upload Status:

GCP: [cloutmad 2019-26-6--15-36-14 Madeleine Clout GCP Refresher Good Clinical Practice Refresher Certificate 24052019.pdf](#)

GCP **24/05/2019**

Date: 

No file chosen

Upload Status:

SUNFLOWER TRIAL MANAGEMENT SYSTEM



- Home
- My Account
- Delegation Log
- Site Files
- Help Videos
- Site Management

Logout

Home

cloutmad

Welcome to the Sunflower Trial Management database.

ACCOUNT SUMMARY

Your Account Status: Approved

CV: [cloutmad_Clout M Short CV 13062018.doc](#)

CV Date: [13/06/2018](#) 

GCP: [cloutmad_2019-26-6--15-36-14_Madeleine Clout GCP Refresher_Good Clinical Practice Refresher Certificate 24052019.pdf](#)

GCP Date: [26/06/2019](#) 

Users awaiting your approval: [7](#)

Users with incomplete Personal training logs: [114](#)

Save

[Please click to here access the Sunflower Patient database.](#)

(Note: The patient database can only be opened on an NHS PC)

Delegation Log - Approval

[Show Email Tool](#)

Trust	Centre	User Login	Name / Email	Initials	Role in Study	Start Date	End Date <input type="checkbox"/> Hide expired	Tasks Performed*	Date Completed	Approve <input type="checkbox"/> Not approved	Personal Training Log <input type="checkbox"/> Not complete	Documentation <input type="checkbox"/> Missing <input type="checkbox"/> Dates Not Set <input type="checkbox"/> Expired
n/a	n/a	sawc	Chas Saw/ charles.saw@uhbristol.nhs.uk	CS	Admin	06/02/2019		43	06/02/2019	Approved <input type="button" value="Unapprove"/>	Complete <input type="button" value="Set Incomplete"/>	<input type="checkbox"/> Uploaded <input type="checkbox"/> Dates Set <input type="checkbox"/> Expired
n/a	n/a	beardchl	Chloe Beard/ chloe.beard@bristol.ac.uk	CB	Admin	11/02/2020		23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 48, 49	11/02/2020	Approved <input type="button" value="Unapprove"/>	Complete <input type="button" value="Set Incomplete"/>	<input checked="" type="checkbox"/> Uploaded <input checked="" type="checkbox"/> Dates Set <input type="checkbox"/> Expired
n/a	n/a	sudjh	David HuttonU/ david.hutton@bristol.ac.uk	DH	Study team, Admin	18/12/2018	18/12/2027	3, 8	18/12/2018	Approved <input type="button" value="Unapprove"/>	Complete <input type="button" value="Set Incomplete"/>	<input checked="" type="checkbox"/> Uploaded <input checked="" type="checkbox"/> Dates Set <input type="checkbox"/> Expired
n/a	n/a	allumemm	Emma Allum/ emma.allum@bristol.ac.uk	EA	Admin	16/01/2019	16/01/2019		16/01/2019	Approved <input type="button" value="Unapprove"/>	Complete <input type="button" value="Set Incomplete"/>	<input checked="" type="checkbox"/> Uploaded <input checked="" type="checkbox"/> Dates Set <input type="checkbox"/> Expired
n/a	n/a	Fran Gill	Fran Gill/ Frances.Gill2@uhbristol.nhs.uk	FG	Admin	25/03/2020		23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 48, 49	25/03/2020	Approved <input type="button" value="Unapprove"/>	Not Complete <input type="button" value="Set Complete"/>	<input checked="" type="checkbox"/> Uploaded <input checked="" type="checkbox"/> Dates Set <input type="checkbox"/> Expired

Master Site File Library

Create... Settings












Document	Version	Status	Last Activity User	Last Activity Date
Home				
Section 1: General Correspondence and Project Management				
Section 2: Screening and Recruitment				
Section 3: Site information and research personnel				
Section 4: Safety reporting				
Section 5: Study specific documentation				
Section 6: Funding arrangements				
Section 7: Agreements				
Section 8: HRA and R&D approval				
Section 9: Research Ethics Committee (REC) approval				
Section 10: Routine data				
Section 11: Sponsorship and insurance				
Section 12: Study registrations				
Section 13: Case Report Form (CRF)/Data Collection				
Section 14: Randomisation				
Section 15: Study Manual				
Section 16: Monitoring and Training				
Section 17: Protocol deviations/breaches				
Section 18: Meetings				
Section 19: Archiving/end of study				
Section 20: Outputs				

Centre Site File Library

CSF (1)

Centre Site File Library

Create... Settings

Document	Version	Status	Last Activity User	Last Activity Date
 Local Site File				
 Section 1: General Correspondence				
 Section 2: Screening and Recruitment				
 Section 3: Site information and research personnel				
 Section 4: Safety reporting				
 Section 5: Localised study documentation				
 Section 6: Local approvals				
 Section 7: Case Report Form (CRF)/Data Collection				
 Section 8: Site initiation, monitoring and training				
 Section 9: Protocol deviations/breaches				
 Section 10: Archiving/end of study				

THE SURVEY

We asked staff at participating sites to complete an online survey to assess user acceptability.

We asked about:

- ❖ Difficulty of using the electronic delegation log and investigator site file
- ❖ Preferences between electronic and paper systems
- ❖ Reasons for these preferences

STUDIES IN THE SURVEY

CIPHER

Cohort study
4,000 patients
75 centres
HTA Ref: 14/166/01

--- .. - - -
C I P H E R
S T U D Y

MONARCH

Diagnostic test
accuracy study
(using iPod apps)
400 patients
6 centres
HTA Ref: 15/97/02

 **MONARCH STUDY**
MONITORING AMD AT HOME

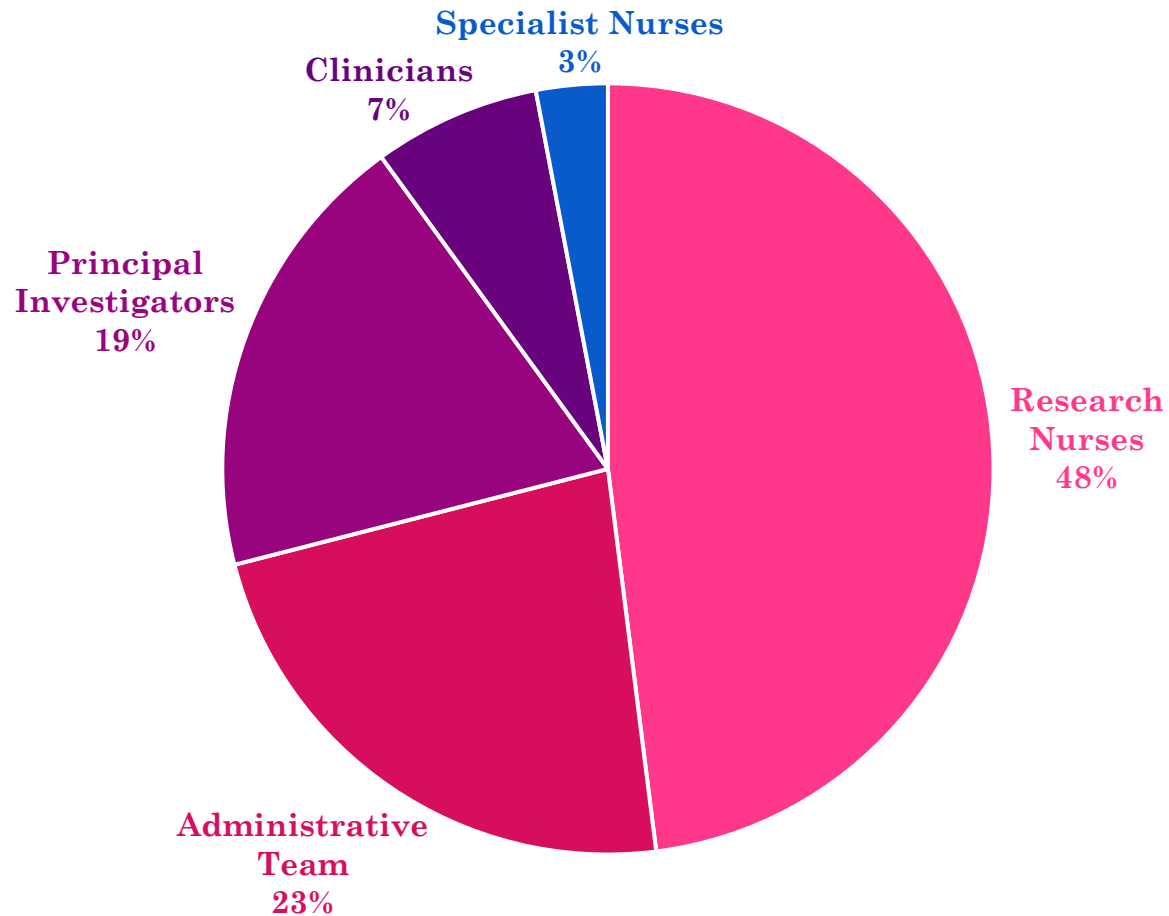
Sunflower

Interventional RCT
13,680 patients
50 centres
HTA Ref: 16/142/04

 The
Sunflower
Study

RESULTS

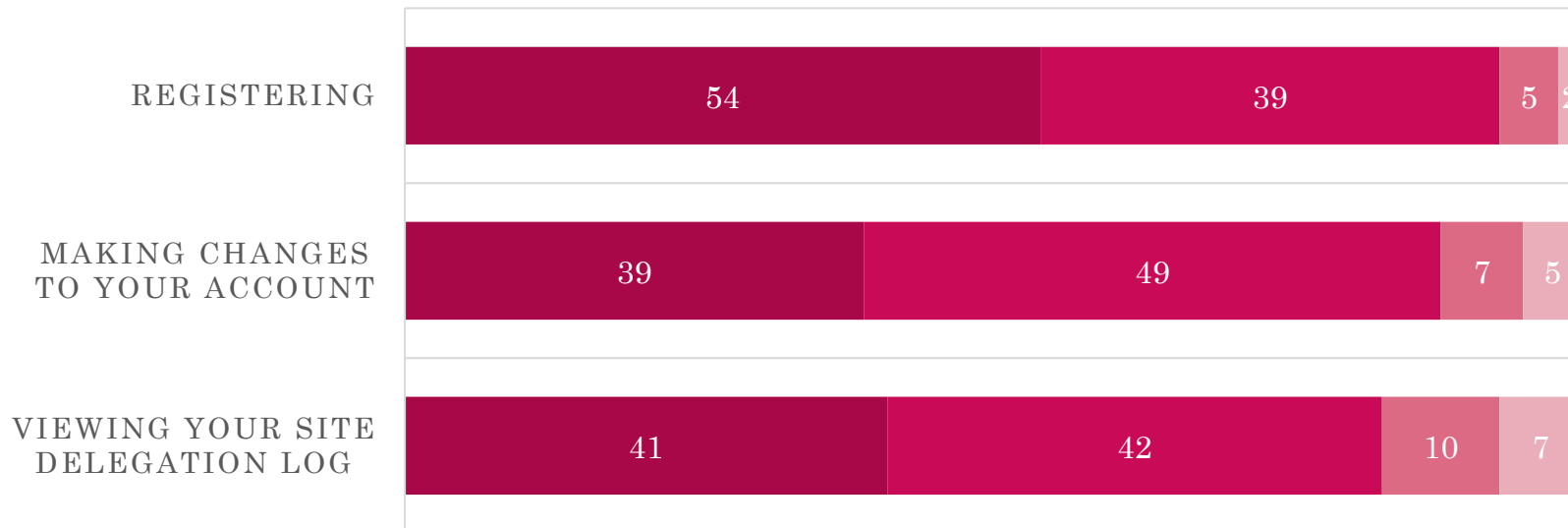
73 responses from 51 participating sites across the 3 studies



RESULTS – Delegation Log

- 84% of responders said they used the electronic delegation log.
- Users were asked to rate the level of difficulty of using aspects of the delegation log:

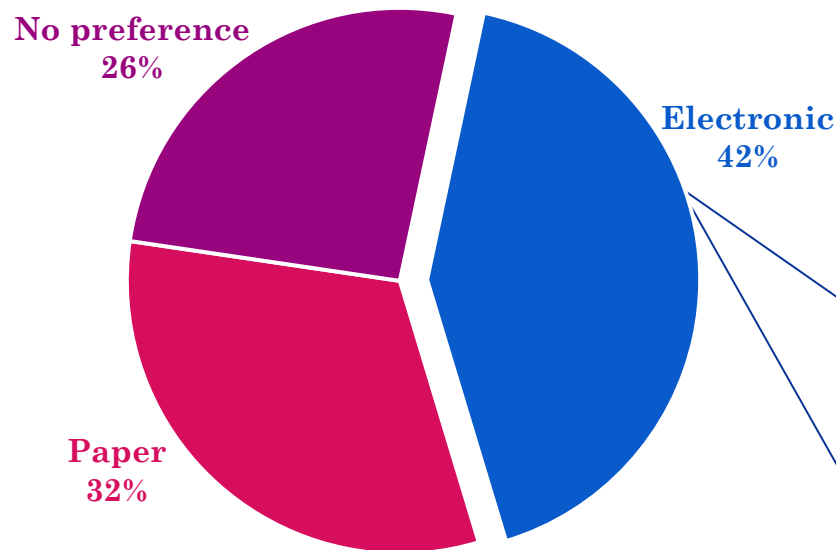
■ Easy (%) ■ Quite Easy (%) ■ Quite difficult (%) ■ Very difficult (%)



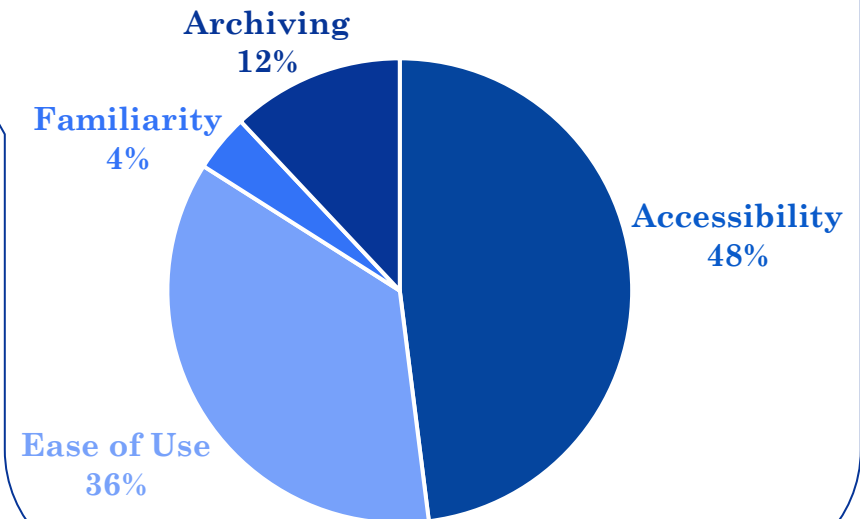
- Overall 87% of users found it either “easy” or “quite easy” to use.

RESULTS – Delegation Log

Format Preference



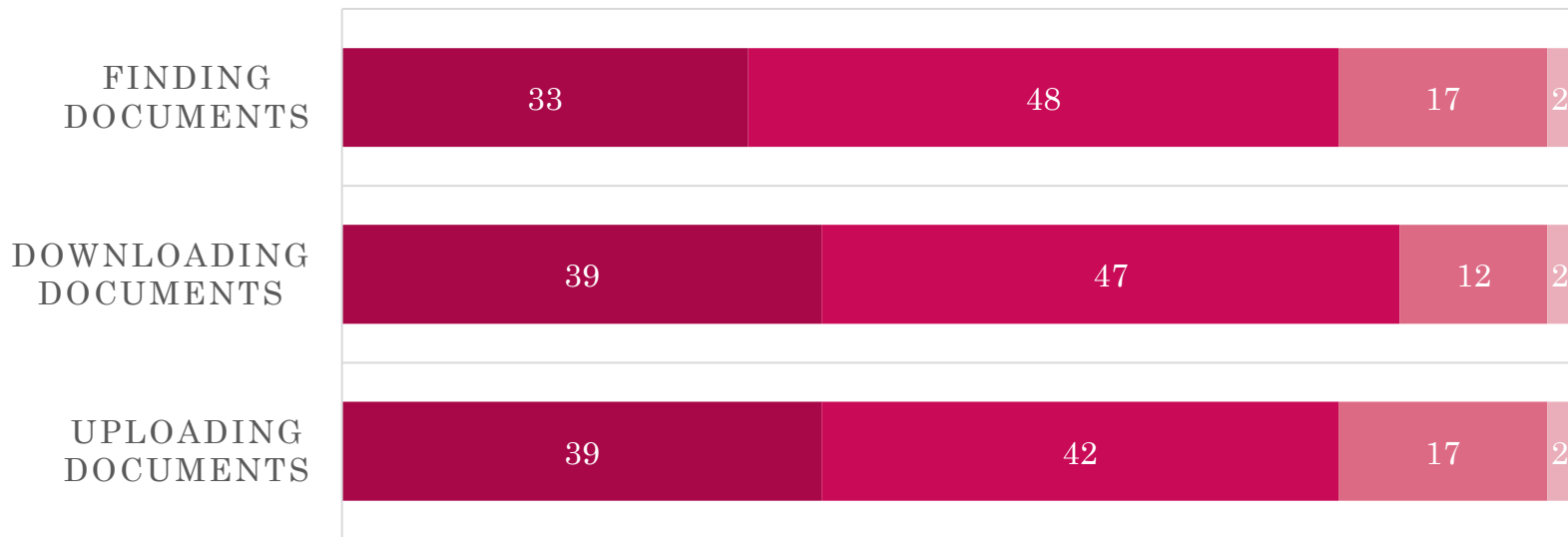
Reasons for Preference for Electronic Log



RESULTS – Investigator Site File

- 66% of responders said they used the electronic site file.
- Users were asked to rate the level of difficulty of using aspects of the site file:

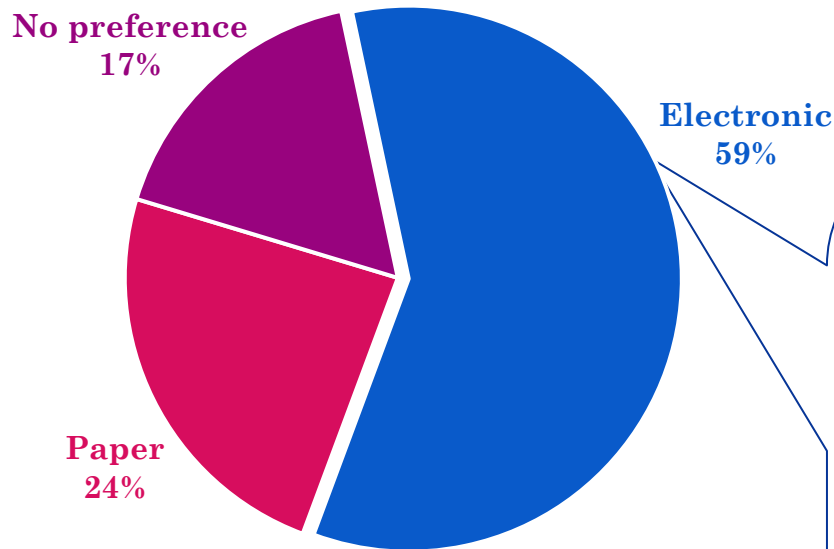
■ Easy (%) ■ Quite easy (%) ■ Quite difficult (%) ■ Very difficult (%)



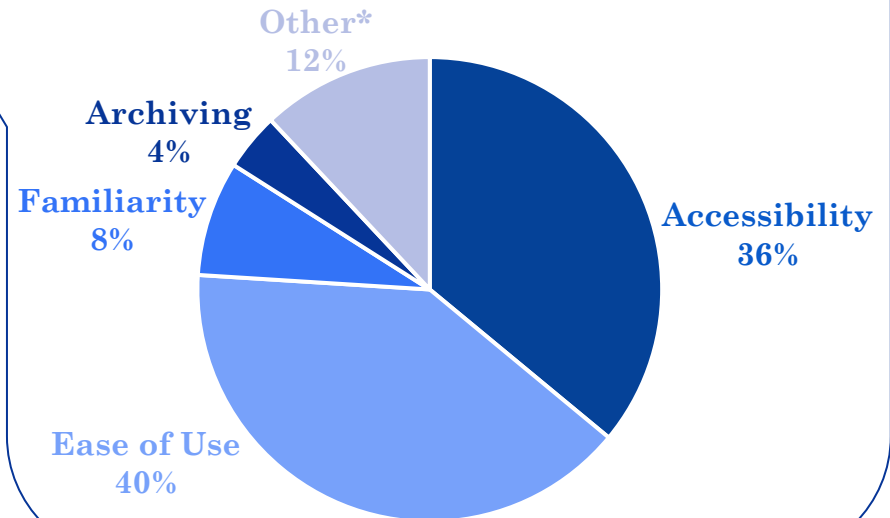
- Overall 81% of users found it either “easy” or “quite easy” to use.

RESULTS – Investigator Site File

Format Preference



Reasons for Preference for Electronic Site File



*Other included: security, version control, quick and always up to date

RESULTS – Study Management System

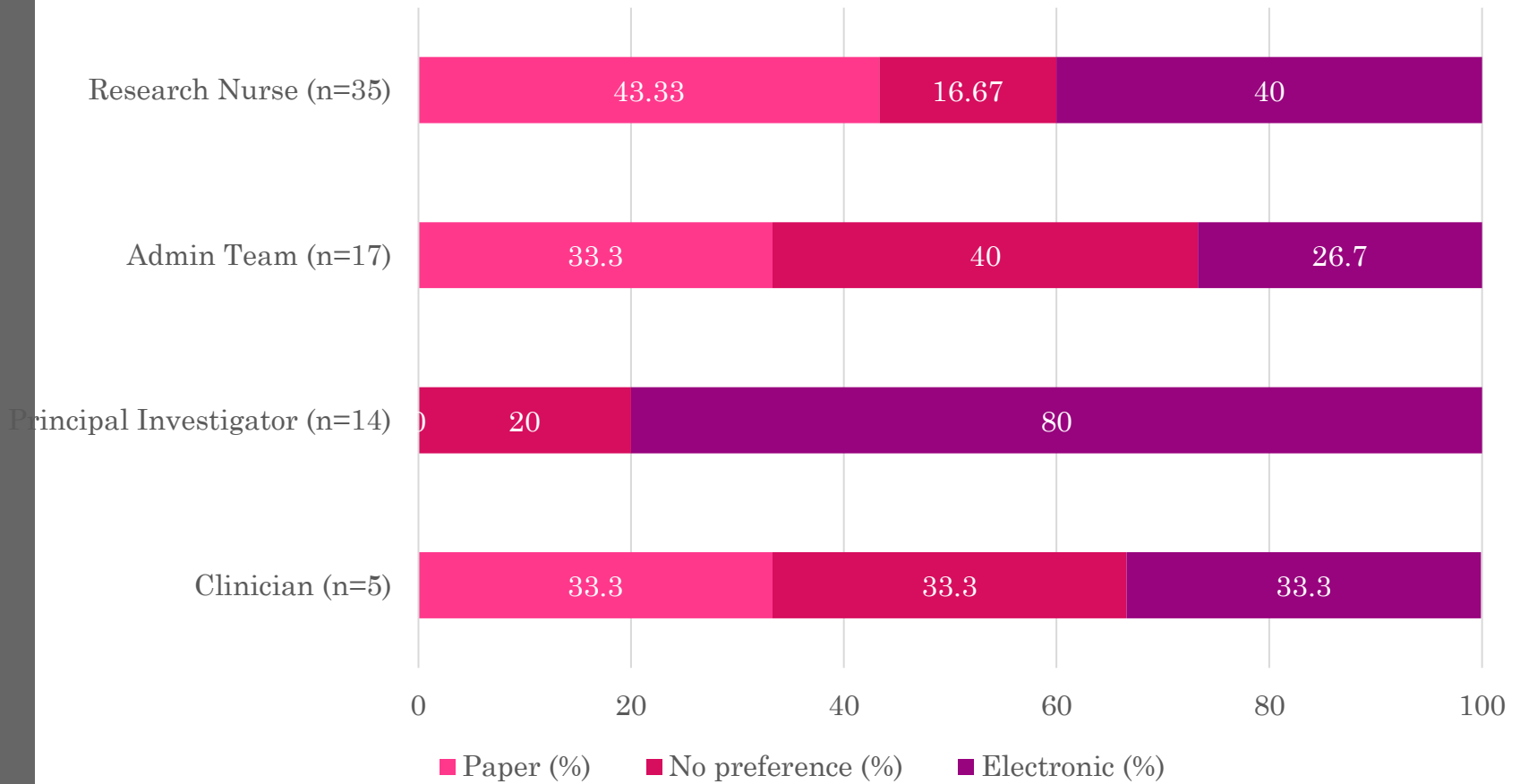
- Users were asked to rate the level of difficulty of navigating the online study management system.

■ Easy ■ Quite easy ■ Quite difficult ■ Very difficult

NAVIGATING
THE SYSTEM

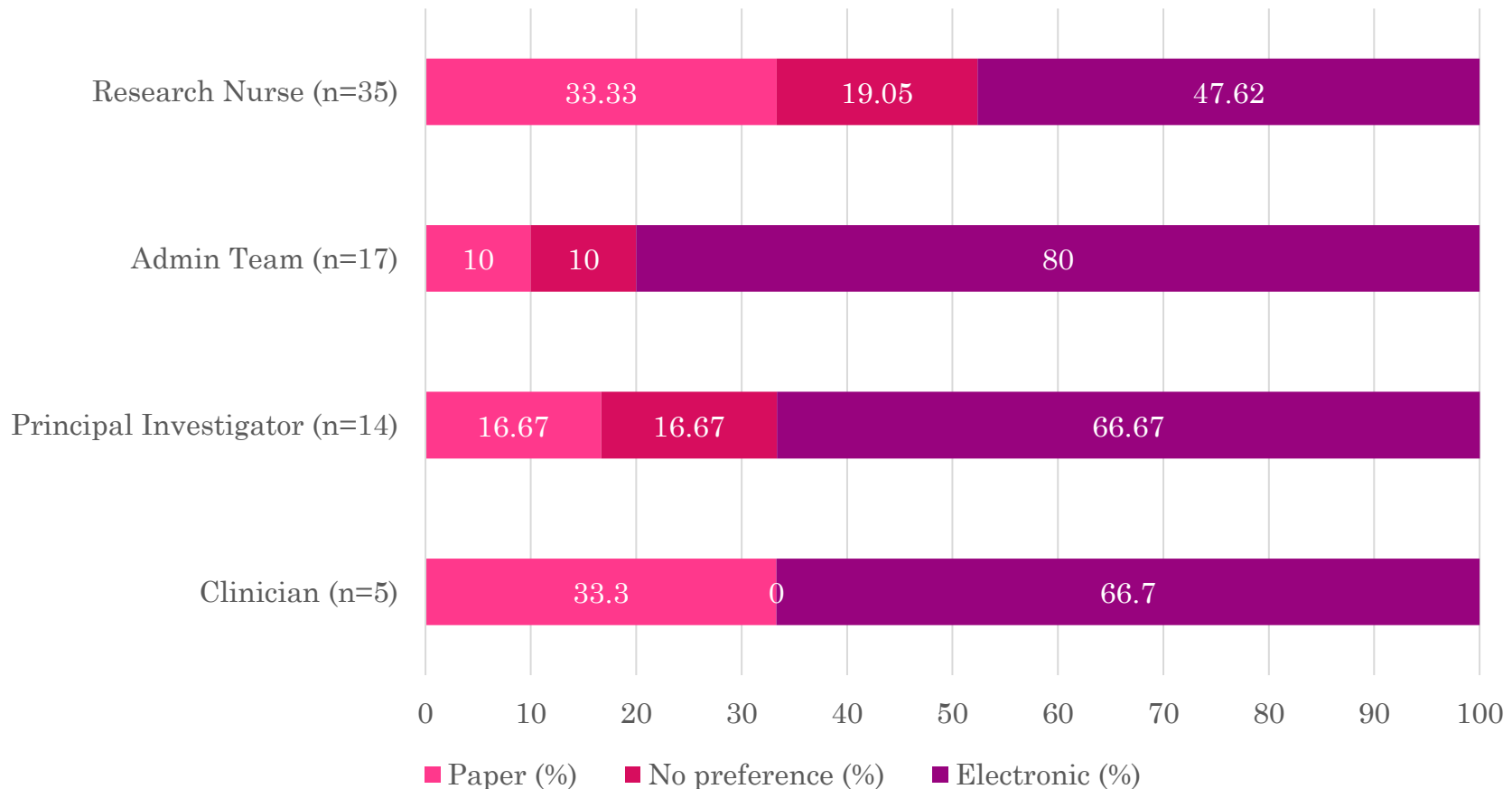


RESULTS – Delegation Log Format Preferences by Staff Group



- From 2 specialist nurse responses, 100% had no preference

RESULTS – Site File Format Preferences by Staff Group



- From 2 specialist nurse responses, 50% preferred electronic and 50% had no preference

RESULTS – Free Text Responses

PROS	CONS
➤ Delegation log sign off is quicker	➤ Need to remember passwords
➤ No chance of documents getting damaged or lost	➤ Some documents still on paper
➤ No back log of paper to file	➤ System can be slow

ELECTRONIC SYSTEM REQUIREMENTS

- Secure log in for users
- Role-based permissions
- Regular back up
- Audit trails
- Training for all users
- Ensuring sites have full control of their eISF
- Providing a copy of the eISF to sites to archive
- Validated system

MHRA INSPECTIONS FOR CTIMPs

- Mapping system for where documents are stored
- Access for monitors and inspectors
- Easy to use system - training provided if required



Medicines &
Healthcare products
Regulatory Agency

CONCLUSIONS

- ❖ Users found the study management system to be accessible and easy to use.
- ❖ This suggests that electronic systems are an acceptable alternative to paper delegation logs and site files.
- ❖ Further consideration must be given to the use of these systems in Clinical Trials of Investigational Medicinal Products.

CLINICAL TRIALS UNIT SURVEY

- Following our presentation at the UKTMN annual meeting, we sent out a request for help to all UKTMN members asking them to get in touch if they were currently using electronic delegation logs and/or site files
- We aimed to determine whether carrying out a similar survey of Clinical Trial Units would be helpful

RESPONSES FROM CLINICAL TRIALS UNITS

- ❖ 18 responses from 12 different organisations (1 affiliation unknown)
- ❖ 3 responders were currently using electronic delegation logs, 4 electronic investigator site files and 1 electronic trial master file
- ❖ 4 responders reported that they were not currently using them, but would like to start using electronic systems
- ❖ Various solutions were reported, including the use of shared drives to create electronic site files/master site file and an electronic delegation log created using REDCap

FURTHER WORK

- A similar survey to assess acceptability to clinical trials unit staff
- Combining the results of these surveys in a publication
- Further development of our in-house systems



NIHR CTU Support Funding

BTC have successfully bid for funding for development of our eTMF system

Aim: To develop a generic system to streamline trial coordination

Output: A system available to other CTUs to manage their studies and interactions with sites, at minimal cost

Timeline: Within the next 12 months

ANY QUESTIONS?



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