

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](mailto: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	<a href="#">sawc</a>	Chas Saw/ <a href="mailto:charles.saw@uhbristol.nhs.uk">charles.saw@uhbristol.nhs.uk</a>	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	<a href="#">beardchl</a>	Chloe Beard/ <a href="mailto:chloe.beard@bristol.ac.uk">chloe.beard@bristol.ac.uk</a>	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	<a href="#">sudjh</a>	David HuttonU/ <a href="mailto:david.hutton@bristol.ac.uk">david.hutton@bristol.ac.uk</a>	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	<a href="#">allumemm</a>	Emma Allum/ <a href="mailto:emma.allum@bristol.ac.uk">emma.allum@bristol.ac.uk</a>	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	<a href="#">Fran Gill</a>	Fran Gill/ <a href="mailto:Frances.Gill2@uhbristol.nhs.uk">Frances.Gill2@uhbristol.nhs.uk</a>	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

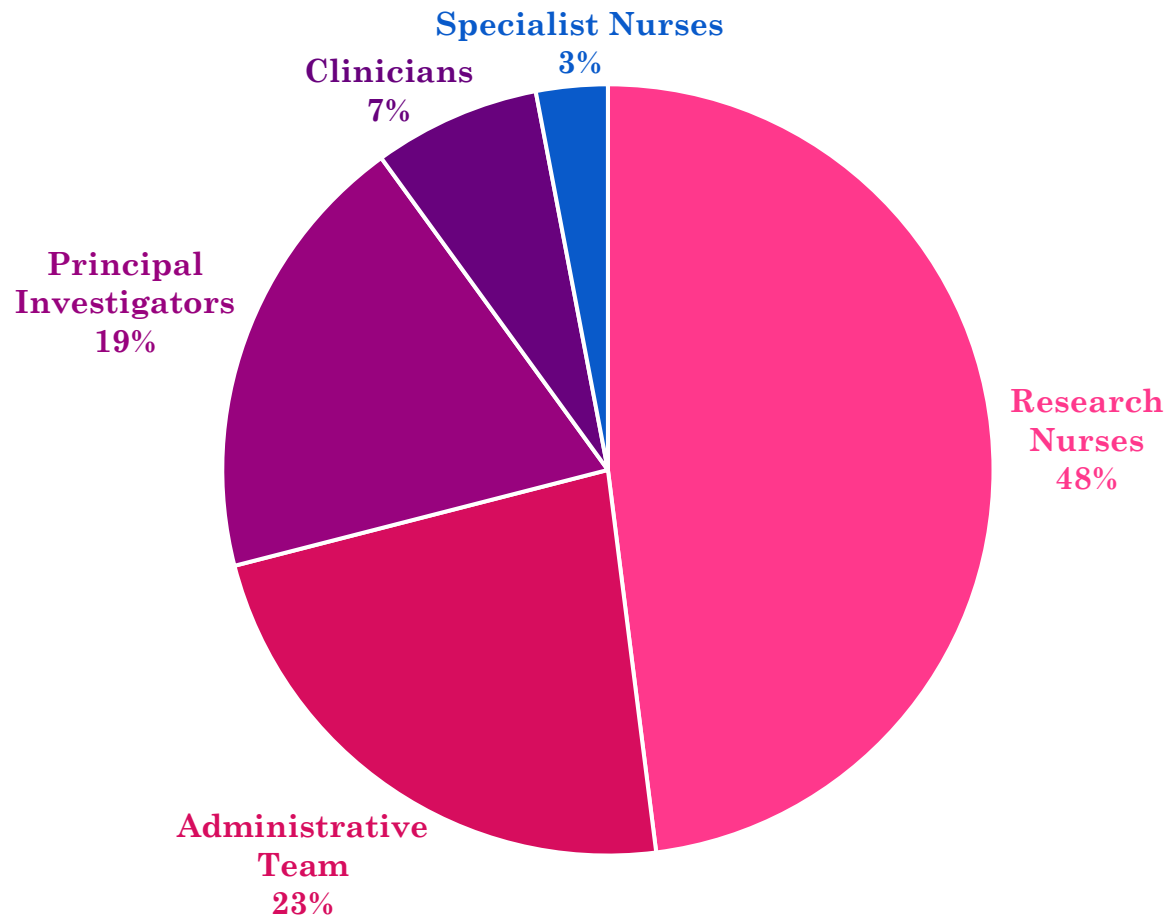
## Sunflower

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

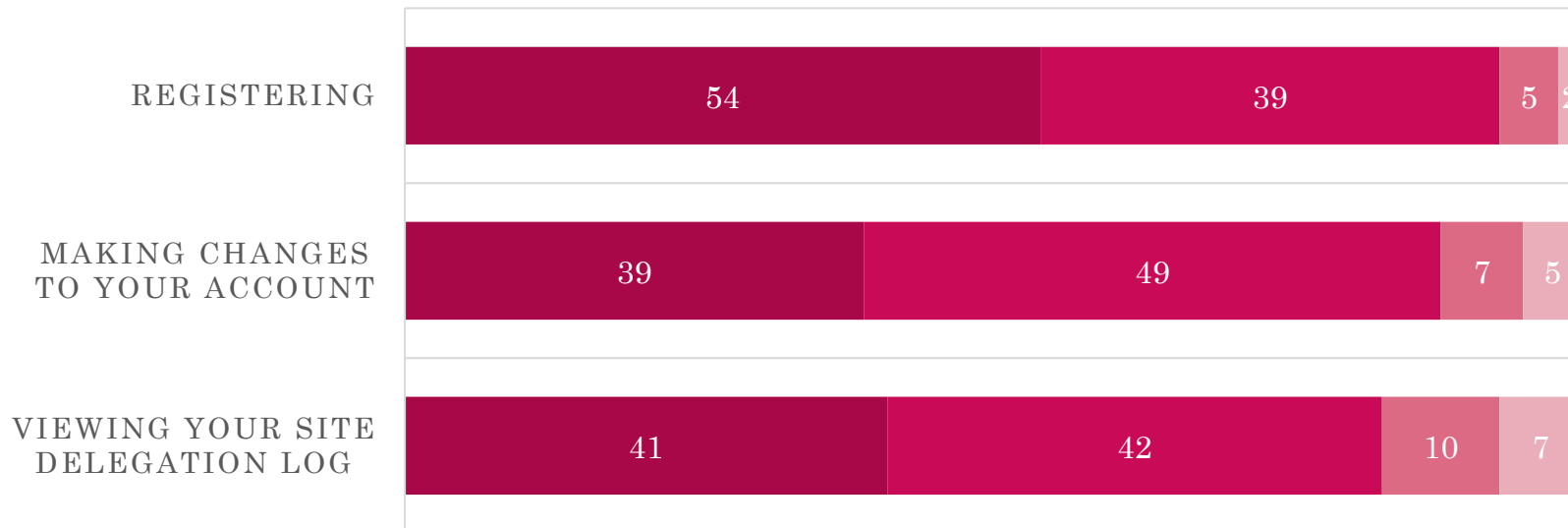




# RESULTS – Delegation Log

- 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:

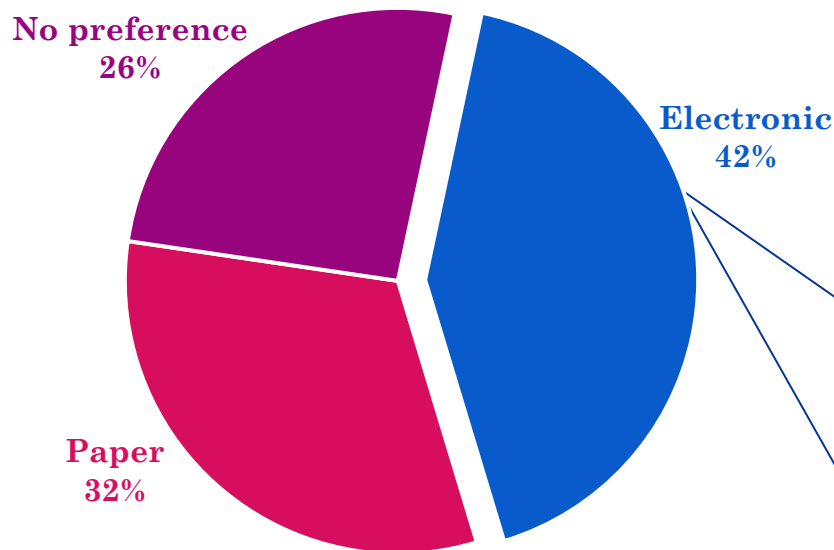
■ Easy (%) ■ Quite Easy (%) ■ Quite difficult (%) ■ Very difficult (%)



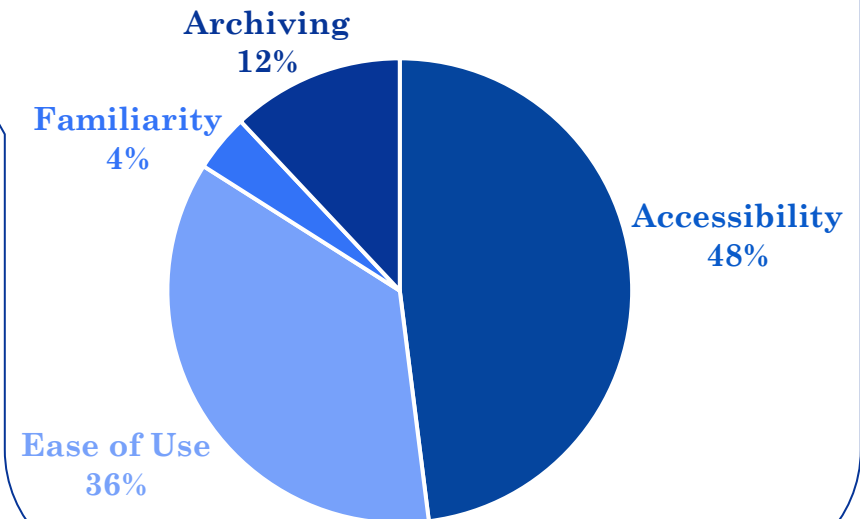
- Overall 87% of users found it either “easy” or “quite easy” to use.

# RESULTS – Delegation Log

## Format Preference



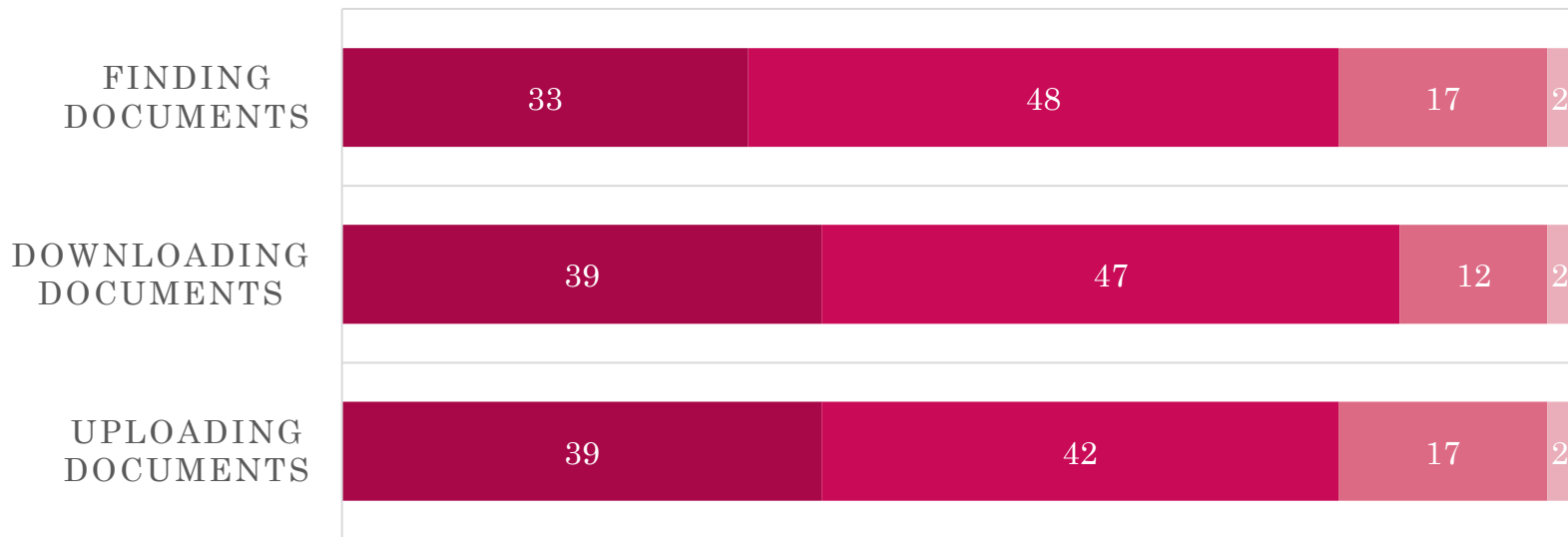
## Reasons for Preference for Electronic Log



# 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:

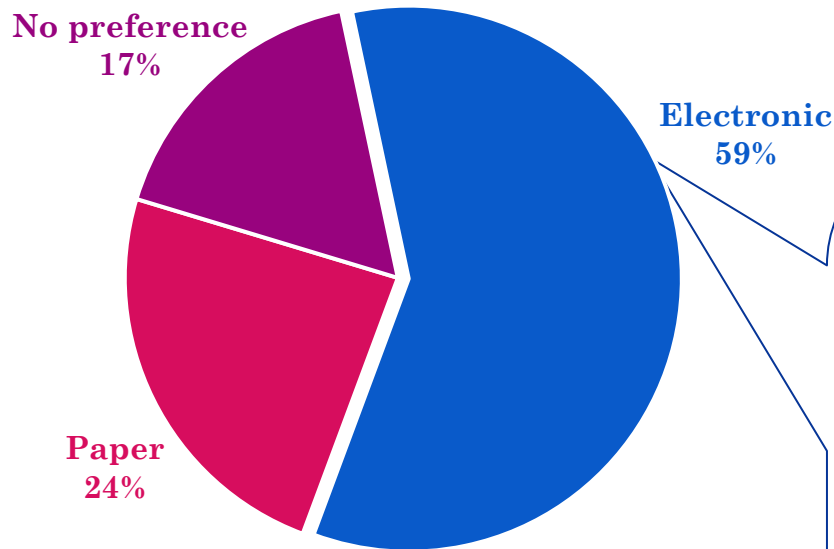
■ Easy (%) ■ Quite easy (%) ■ Quite difficult (%) ■ Very difficult (%)



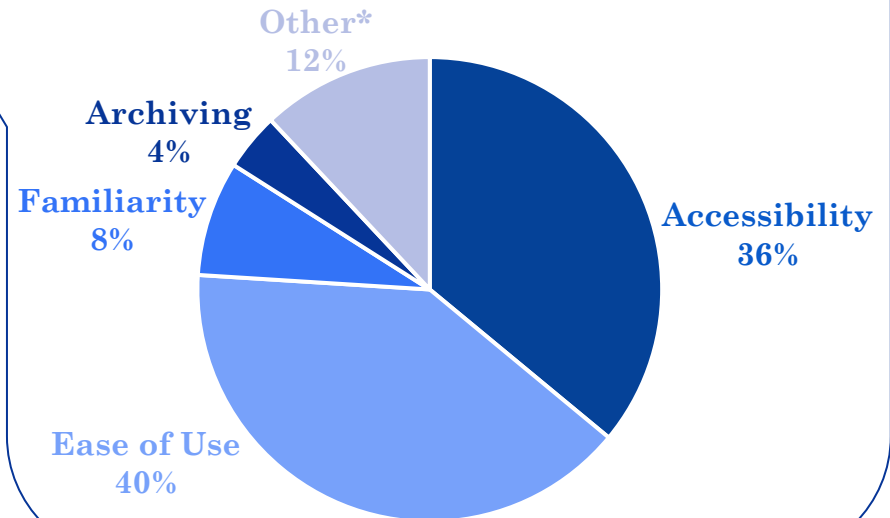
- Overall 81% of users found it either “easy” or “quite easy” to use.

# 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

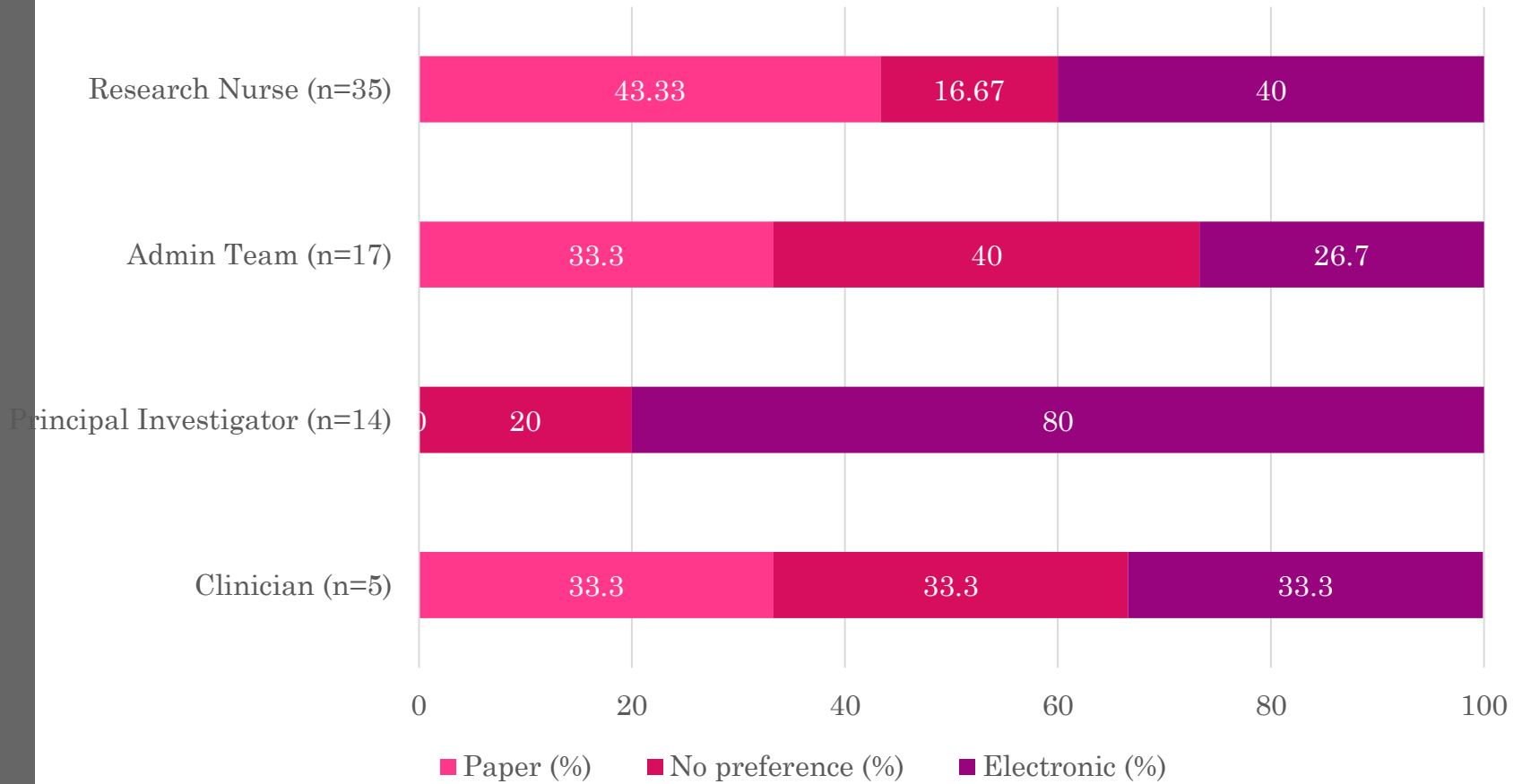
- Users were asked to rate the level of difficulty of navigating the online study management system.

■ Easy   ■ Quite easy   ■ Quite difficult   ■ Very difficult

NAVIGATING  
THE SYSTEM

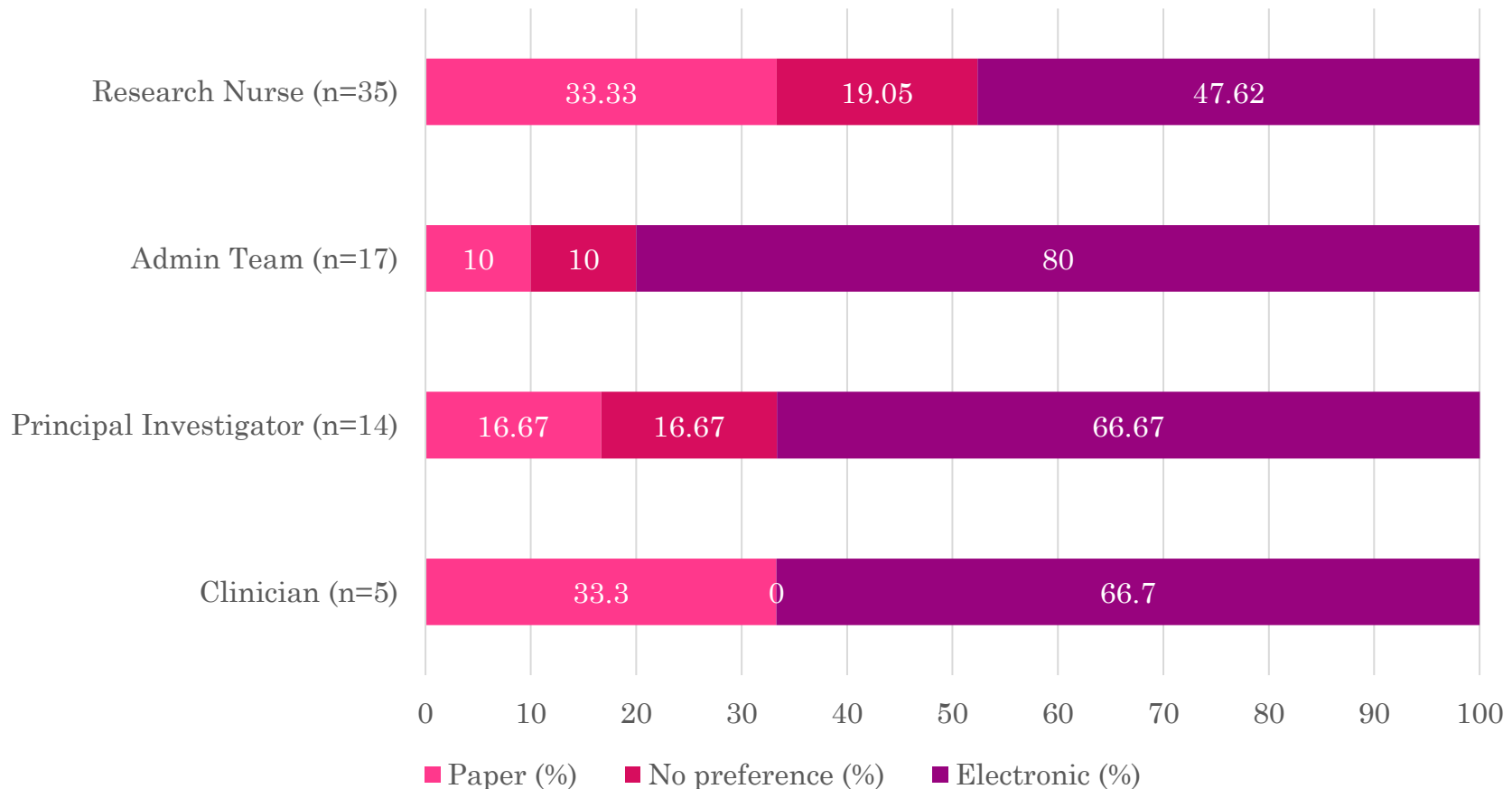


# RESULTS – Delegation Log Format Preferences by Staff Group



- 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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