Knowledge of Health Systems Data use in clinical trials

* Required

Participant Information

You have been invited to complete this survey as you currently work in clinical trials.

We are a team of researchers working with Health Data Research UK seeking to understand the current levels of knowledge among clinical trials staff around the use of Health Systems Data (HSD) in trials. Health Systems Data are a form of longitudinal, real-world data that contain patient information on healthcare interactions, such as hospitalisations and mortality. This survey will explore your knowledge and experience of HSD use in clinical trials. Even if you have not used HSD, we still need to hear from you!

The survey will around 15-20 minutes to complete. It is up to you to decide whether or not to take part. You may withdraw at any time without giving a reason and without penalty. Any information provided can be withdrawn up to **17th October 2025**. Once the survey closes, all data will be anonymised and is therefore you will be unable to be withdrawn beyond this time.

There are no risks to participating in this survey. Whilst there are no immediate benefits to taking part, we hope that the findings of this survey will inform future development of the use of HSD in clinical trials. Data collected will be kept in a secure environment until the end of the project in **April 2028.** No other use will be made of this data and no one outside the project will be allowed access to the data collected.

All the information that we collect about you during the course of the research will be kept strictly confidential. You will not be able to be identified in any ensuing reports or publications. Results are likely to be presented at conferences and be published in an academic journal or as a report for the project funders.

Data Protection Privacy Notice

The data controller for this project will be University College London (UCL). The UCL Data Protection Office provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk. UCL's Data Protection Officer can also be contacted at data-protection@ucl.ac.uk.Further information on how UCL uses participant information can be found here: www.ucl.ac.uk/legal-services/privacy/participants-health-and-care-research-privacy-notice. Your personal data will be used for the purposes outlined in this notice. The categories of personal data used will be as follows:

- Name
- Email address
- Job position
- Place of work

The legal basis that would be used to process your personal data will be performance of a task in the **public interest**. *Y*our personal data will be processed so long as it is required for the research project. If we are able to anonymise or pseudonymise the personal data you provide we will undertake this, and will endeavour to minimise the processing of personal data wherever possible. You have certain rights under data protection legislation in relation to the personal information that we hold about you. These rights apply only in particular circumstances and are subject to certain exemptions such as public interest (for example the prevention of crime). They include:

- The right to access your personal information
- The right to rectification of your personal information
- The right to erasure of your personal data
- The right to restrict or object to the processing of your personal data
- The right to object to the use of your data for direct marketing purposes
- The right to data portability
- Where the justification for processing is based on your consent, the right to withdraw such consent at any time
- The right to complain to the Information Commissioner's Office (ICO) about the use of your personal data

If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk. If you remain unsatisfied, you may wish to contact the ICO. Contact details and further details of the data subject rights are available on the ICO website at: https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/.

This study is funded by Health Data Research UK and has been approved by the UCL Research Ethics Committee [project ID:1697]. By completing the survey, you are providing your consent to participate in this study. Your contributions will be anonymous, which means that your responses cannot be traced back to you. For this reason, any data that you enter whilst completing the survey cannot later be withdraw. If you have any questions, complaints or would like any more information about the survey, please contact **Dr Macey Murray: macey.murray@ucl.ac.uk.**

Consent Form

If you are happy to complete the survey, you will need to provide your consent by answering *YES* to all of the questions below:

1. I confirm that I have read and understood the information provided. *

- ◯ Yes
- ◯ No

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason. *

- ◯ Yes
- ◯ No

3. I understand that my data will be analysed and be kept until the end of the project in April 2028. *

- ◯ Yes
- ◯ No

4. I understand that my participation and the data collected will be kept confidential. *

- ◯ Yes
- ◯ No

5. If understand that if I withdraw from the study after the closing date of the survey, any data provided by me will be kept and processed. *

- ◯ Yes
- ◯ No

6. I understand that providing my email address is not compulsory to complete the survey. However, if I wish to enter the prize draw, be provided updates about the survey or future work in HSD my email address will be collected and stored until the end of the project in April 2028. *

- ◯ Yes
- ◯ No

General Information

7. Do you currently work in clinical trials in the United Kingdom? *

- ◯ Yes
- ◯ No

8. Which country are you based in? *

- ◯ England
- ◯ Scotland
- ◯ Wales
- ◯ Northern Ireland

9. What is your job/role? *

- ◯ Chief Investigator / Principal Investigator
- ◯ Clinical Project Manager
- ◯ Data Analyst
- ◯ Data Management Specialist
- ◯ Data Manager
- ◯ Data Scientist
- ◯ Database Programmer
- ◯ Project / Programme Lead
- ◯ Quality Assurance Manager
- ◯ Quality Assurance Officer
- ◯ Safety/Pharmacovigilance Manager
- ◯ Safety/Pharmacovigilance Officer
- ◯ Senior Trial Manager
- ◯ Statistician
- ◯ Trial Administrator
- ◯ Trials Assistant
- ◯ Trial Clinician
- ◯ Trial Manager
- ◯ Other

10. Where do you currently work? (name/reg number of CTU/institution) *

11. What disease area(s) do you currently work in? *

12. How long have you been in your current role? *

- ◯ <1 year
- ◯ 1-9 years
- ◯ 10-19 years
- ◯ >20 years

13. How long have you worked in clinical trials overall? *

- ◯ <1 year
- ◯ 1-9 years
- ◯ 10-19 years
- ◯ >20 years

14. Are you a member of the HDR UK Transforming Data for Trials Community Insight Group (CIG)? *

- ◯ Yes
- ◯ No

Involvement with Health Systems Data

15. Have you ever used Health Systems Data for trial(s) you have worked on? (e.g., Electronic Health Records, Registry data) *

- ◯ Yes
- ◯ No

16. How long have you been involved in working with Health Systems Data (in years)? *

17. Are you currently working on a trial that has accessed / used Health Systems Data? *

- ◯ Yes
- ◯ No

18. What are the reasons you have not accessed / used Health Systems Data? *

- ☐ Too long to gain access
- ☐ Too costly to gain access
- ☐ Low quality of the data
- ☐ Other

19. For which trial(s)? *

20. Which areas of Health Systems Data use are/were you involved in? *

- [ ] Communication with data providers
- [ ] Data access
- [ ] Data costs
- [ ] Data governance
- [ ] Data utility
- [ ] Obtaining / Receiving data
- [ ] Preparing data
- [ ] Managing data
- [ ] Analysing data
- [ ] Archiving data
- [ ] Onward sharing of data
- [ ] Other

Knowledge of Health Systems Data

21. In relation to HSD use in clinical trials, how would you rate your knowledge if the following aspects of **trial design/management** ?

	I have no knowledge	I have a little knowledge	I have some knowledge	I have a lot of knowledge	I have expertise in this area
Costing	○	○	○	○	○
Determining the data required for analysis	○	○	○	○	○
Inclusivity and engaging underserved groups	○	○	○	○	○
Risk Assessment	○	○	○	○	○
Safety monitoring/pharmacovigilance	○	○	○	○	○

22. How would you rate your knowledge of the following areas of the HSD **approvals** process?

	I have no knowledge	I have a little knoweldge	I have some knowledge	I have a lot of knowledge	I have expertise in this area
When to apply for approval	○	○	○	○	○
Differences in requirements between data providers	○	○	○	○	○
Differences in requirements between devolved nations	○	○	○	○	○
Differences in processes for nationally, regionally and locally collected/stored data	○	○	○	○	○
Information governance requirements	○	○	○	○	○
Approval duration	○	○	○	○	○
Amendments to approvals	○	○	○	○	○

23. How would you rate your knowledge about the following areas of **informed consent** in relation to HSD access/use?

	I have no knowledge	I have a little knowledge	I have some knowledge	I have a lot of knowledge	I have expertise in this area
The lawful basis for accessing HSD	◯	◯	◯	◯	◯
The role of Section 251 (England and Wales) or Public Benefit Privacy Panel (Scotland)	◯	◯	◯	◯	◯
Importance of transparency	◯	◯	◯	◯	◯
The right to withdraw	◯	◯	◯	◯	◯
HRA guidance for GDPR and PIS requirements	◯	◯	◯	◯	◯
Managing changes in participants' mental capacity	◯	◯	◯	◯	◯

24. How would you rate your knowledge of the following areas of HSD use in relation to site **feasibility and selection**?

	I have no knowledge	I have a little knowledge	I have some knowledge	I have a lot of knowledge	I have expertise in this area
HSD in site feasibility assessment	◯	◯	◯	◯	◯
HSD in site/investigator selection process	◯	◯	◯	◯	◯
HSD in identifying populations for recruitment	◯	◯	◯	◯	◯

25. How would you rate your knowledge of the following areas of **contracts and agreements** for HSD access/use?

	I have no knowledge	I have a little knowledge	I have some knowledge	I have a lot of knowledge	I have expertise in this area
Data controllers	◯	◯	◯	◯	◯
Data processors	◯	◯	◯	◯	◯
The role of your organisation	◯	◯	◯	◯	◯
The importance of contracting	◯	◯	◯	◯	◯
Data Protection Impact Assessments (DPIAs)	◯	◯	◯	◯	◯
Data Sharing Agreements	◯	◯	◯	◯	◯
Data Processing Agreements	◯	◯	◯	◯	◯
Timelines for Data Sharing Agreements and renewals	◯	◯	◯	◯	◯

26. How would you rate your knowledge of the following areas of **Protocol development?**

	I have no knowledge	I have a little knowledge	I have some knowledge	I have a lot of knowledge	I have expertise in this area
RECORD guidelines	◯	◯	◯	◯	◯
CONSORT-ROUTINE Guidelines	◯	◯	◯	◯	◯

27. How would you rate your knowledge of the following areas of HSD **data management and analysis**?

	I have no knolwedge	I have a little knowledge	I have some knowledge	I have a lot of knowledge	I have expertise in this area
Primary care datasets	◯	◯	◯	◯	◯
Registries, Audits and clinical cohorts	◯	◯	◯	◯	◯
Using Trusted Research Environments (TREs)/ Secure Data Environments (SDEs)	◯	◯	◯	◯	◯
Using HSD for sample size estimations/calculations	◯	◯	◯	◯	◯
Using algorithms for the assessment of relevant outcomes	◯	◯	◯	◯	◯
Using coding and phenotype libraries	◯	◯	◯	◯	◯
Using synthetic data	◯	◯	◯	◯	◯
Using derived data	◯	◯	◯	◯	◯
Data Utility (fitness-for-purpose)	◯	◯	◯	◯	◯
Dealing with missing data	◯	◯	◯	◯	◯

28. How would you rate your knowledge of the following areas of **archiving and data sharing**?

	I have no knowledge	I have a little knowledge	I have some knowledge	I have a lot of knowledge	I have expertise in this area
Understanding data provider requirements	◯	◯	◯	◯	◯
Feeding back to data providers	◯	◯	◯	◯	◯
Data ownership	◯	◯	◯	◯	◯
De-identification/anonymisation of data	◯	◯	◯	◯	◯
Onward sharing of data	◯	◯	◯	◯	◯

29. If you need to refer to guidance for information about using HSD in your trial, where would you search for it? *

- ☐ Local departmental/unit SOPs
- ☐ MHRA Guidance
- ☐ EU Guidance
- ☐ FDA Guidance
- ☐ Medicines for Human Use (Clinical Trials) Regulations
- ☐ ICH GCP
- ☐ I don't know
- ☐ Other

30. How confident are you about using HSD in your trial(s)? *

Very confident	Somewhat Confident	Slightly Confident	Not at all Confident
◯	◯	◯	◯

31. Briefly explain your answer *

Patient and Public Involvement and Engagement (PPIE)

32. How experienced are you with engaging in PPIE relating to HSD use in trials? *

- ◯ I have no experience
- ◯ I have a little experience
- ◯ I am somewhat experienced
- ◯ I am very experienced

33. What level of involvement did PPIE representatives have in your trial? *

- ◯ We had no PPIE involvement
- ◯ PPIE representatives were informed
- ◯ PPIE representatives were consulted
- ◯ PPIE representatives were involved
- ◯ PPIE representatives co-produced/co-designed the work
- ◯ PPIE representatives took a leadership role
- ◯ Other

34. How confident do you feel about incorporating PPIE in the context of HSD use in trials?

- ◯ Not at all confident
- ◯ Slightly confident
- ◯ Somewhat confident
- ◯ Very confident

Training and learning preferences

We would like to know what the gaps are in your knowledge and be able to better support the use of HSD in trials.

35. Where do you feel your knowledge gaps are?

36. What do you feel could be done to improve your confidence in using HSD effectively?

37. Rank your preferred learning format from **most** to **least** preferred

- Asynchronous/self-paced online
- Case studies
- Drop-in clinic (in person)
- Drop-in clinic (online)
- Hybrid remote/in person
- In person workshop/training day
- Online guidance
- Synchronous online
- Webinars
- Other

HDR UK Futures Training

38. Have you heard of the **HDR UK Futures** online training platform?

- ◯ Yes
- ◯ No

39. **Futures** is a free learning platform, featuring courses and events created and taught by experts in health data science. Whether you are just starting out in data science, or looking to learn how to apply your data science skills to a health context, there is something for you on **Futures**:

    https://www.hdruk.ac.uk/study-and-train/learn-with-hdr-uk-futures/ *

- ◯ Continue to next question

40. Have you completed any of the **HDR UK Futures** online training packages? *

- ◯ Yes
- ◯ No

41. Which of the following **HDR UK Futures** online training packages have you completed?

- ☐ Accessing health data
- ☐ An introduction to data enabled clinical trials
- ☐ Data-enabled trials - bitesize topics
- ☐ Data Utility considerations for clinical trials
- ☐ Routine data in clinical trials: building public trust

42. Do you still feel there are gaps in your knowledge? *

- ◯ Yes
- ◯ No

43. What are the gaps? *

44. Overall, how useful was this training?

Extremely useful	Somewhat useful	Not very useful	Not at all useful
◯	◯	◯	◯

45. What are your reasons for not completing any training on **HDR UK Futures**? (Select all that apply)

- ◯ I have not had time
- ◯ Have have not used HSD
- ◯ I'm not planning to use HSD
- ◯ The training didn't seem to cover what I needed it to
- ◯ I already have adequate knowledge/expertise in using HSD
- ◯ I was not aware of the HRD UK Futures platform
- ◯ Other

Mentorship and support

46. Would you consider accessing support from a mentor to learn how to effectively use HSD?

- ◯ Yes
- ◯ No
- ◯ Maybe

47. Briefly explain your answer *

48. Would you be willing to be involved in the development of a mentoring scheme?

- ◯ Yes
- ◯ No
- ◯ Maybe

49. Briefly explain your answer *

50. Would you be willing to act as a mentor to support people to use HSD in their trials?

- ◯ Yes
- ◯ No
- ◯ Maybe

51. Briefly explain your answer *

52. Would you consider joining a support group to learn how to use HSD? *

- ◯ Yes
- ◯ No
- ◯ Maybe

53. Briefly explain your answer *

Data Utility Comparison Studies (DUCkS)

In DUCkS, relevant data collected through traditional trial-specific data collection is compared to data obtained through health systems (such as hospital admissions databases). These help trialists determine whether Health Systems Data are relevant and capture what is needed for the trial outcome (Sydes et al, 2024).

54. Have you heard of Data Utility Comparison Studies (DUCkS) before? *

- ◯ Yes
- ◯ No

55. Where did you first hear about DUCkS? *

56. Have you worked on a trial that completed a DUCkS? *

- ◯ Yes
- ◯ No

57. What were the findings from your DUCkS? (complete all that apply)

	Poor ≤20%	Fair 21-40%	Moderate 41-60%	Substantial 61-80%	Almost perfect 81-99%	Perfect 100%
Agreement/concordance was...	◯	◯	◯	◯	◯	◯
Sensitivity was...	◯	◯	◯	◯	◯	◯
Specificity was...	◯	◯	◯	◯	◯	◯

58. If your DUCkS was published, please insert the reference link (e.g. DOI) here

59. What do you think are the barriers to completing DUCkS? *

60. Have you completed any DUCkS training? *

- ◯ Yes
- ◯ No

61. What training have you completed? (Select all that apply) *

- [ ] HDR Futures Data Utility Considerations for Clinical Trials
- [ ] DUCkS workshop
- [ ] Other

Other

62. Is there anything else about using HSD in trials that you would like to mention that has not been covered? *

Contact details

Thank you for taking the time to complete this survey. Please enter your email address below if you would like to be entered into the prize draw and/or contacted about the results or future work in this area.

63. Please enter your email address below

64. Select all that apply

- [ ] I would like to be entered into the prize draw
- [ ] I would like to be contacted about the results of the survey
- [ ] I am happy to be contacted about future work relating to the use of HSD in clinical trials
- [ ] I would like to be contacted to share my experiences from successful & unsuccessful attempts to use HSD in clinical trials
- [ ] I would be interested in joining the Community Insight Group (CIG)

Survey awareness

Just one last thing...We'd really like to know how you heard about our survey.
Once again we'd like to take the opportunity to thank you for taking part in this survey.

65. How did you hear about this survey? *

- [ ] Email from HDR UK Transforming Data for Trials group
- [ ] UKTMN Newsletter
- [ ] MRCCTU Weekly news
- [ ] CCTU Weekly news
- [ ] UK CTC Weekly news
- [ ] Priment weekly news
- [ ] TMRP message/noticeboard
- [ ] Royal Society for Statistics
- [ ] NIHR Statistics Group
- [ ] X
- [ ] BlueSky
- [ ] LinkedIn
- [ ] Other

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