

# Sharing individual participant data from clinical trials: experience over 5 years in the NCTU

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## Background

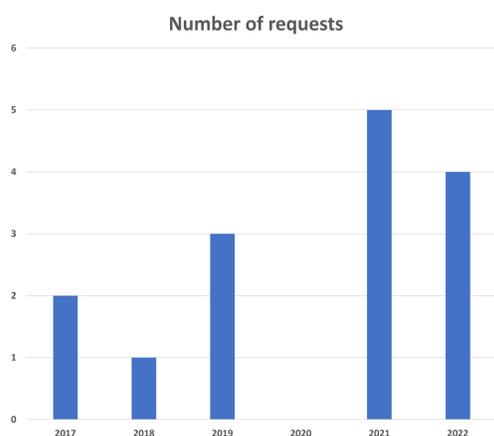
Although the sharing of de-identified individual participant data is not mandated as yet, it is strongly encouraged as a means to minimise research waste. The ICMJE introduced a requirement for a data sharing statement to be included in each newly submitted paper (effective 1 July 2018) and pre-specified in study registration (effective 1 January 2019)<sup>1</sup>. Similarly many funders also now require a data sharing statement (eg UK's NIHR)<sup>2</sup>.

The Nottingham Clinical Trials Unit (NCTU) adopted a controlled access policy and developed a data sharing SOP in 2017. We have conducted an evaluation of our processes using the information collected over the five year period since its introduction.

## Methods

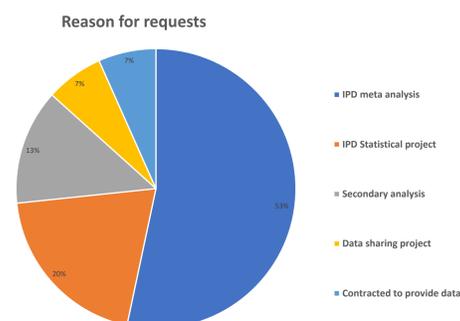
We summarised the number of requests received by the NCTU over the 5 year period from 2017 to 2022. We examined the reasons data were being requested, from where, and the times from request to data sharing committee meeting, data sharing agreement and release of data.

## Results

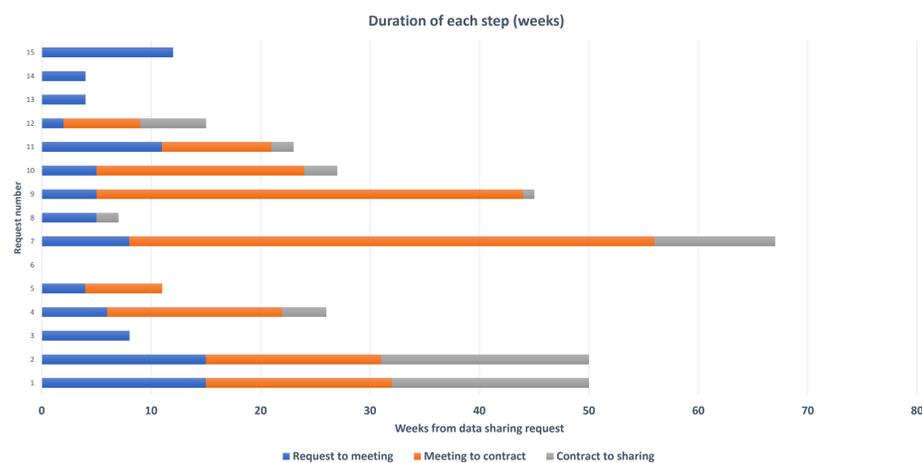


**Number and location of requests:** 15 requests for data from 12 trials. 1 request was withdrawn, one was 'lost to follow up' at the data sharing agreement stage, 10 were fulfilled and 3 requests are still outstanding. 11 requests were from UK researchers and there was 1 request each from Australia, Norway, the Netherlands and Ireland

**Reasons for requests :** 8 requests were for data to use in IPD meta analyses, 3 for use in statistical projects, 2 for secondary analyses, 1 for use in a specific data sharing project and 1 was requested as there had been a pre-trial contractual agreement. 13 requests were from academic researchers and 2 were from commercial companies.



**Time to fulfil data sharing requests:** The duration of each step is shown below. The requests are in order with request 1 the first received in 2017 and 15 the last received in 2022. Request 6 was withdrawn prior to the meeting. Summary statistics are also shown.



	Mean (SD)	Min, Max
Weeks from request to meeting	7 (4.2)	2, 15
Weeks from request to signed agreement	25 (15.8)	5, 56
Weeks from request to sharing	31 (19.9)	6, 67

## Conclusions

- Data sharing can take a considerable amount of time.
- In general the majority of time in the process is taken with the time from the data sharing committee meeting to the data sharing agreement being signed by all parties.
- The time from the data sharing request to the data sharing committee meeting is often dictated by the availability of key members of the committee (the CI and the sponsor)
- In the NCTU we are seeing an improvement in the time to the data sharing agreement being signed by all parties as our main sponsors have developed templates and processes for these agreements.
- Where the agreement is with a non-UK team, there may be requirements for further checks before a data sharing agreement can be signed.
- Delays may be caused if the request is for older trials where the data has not been prospectively de-identified, and where trial staff have left or have been reassigned.

<sup>1</sup>Taichman DB, Sahni P, Pinborg A, et al. Data sharing statements for clinical trials: a requirement of the International Committee of medical Journal editors. *Ann Intern Med* 2017;**167**:63–5. doi:10.7326/M17-1028

<sup>2</sup><https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253>

