

Supplementary Appendix 1: Supplementary quotes from researchers and data providers

Theme	Supplementary quotes
Communication	"As an example, everybody in the research environment seems to understand what it means to sponsor a study, and I've had numerous definitions of this and still don't have a concrete view." (DP2) "It's the ability to step outside what you know, and view the same subject from the perspective of a lay person... it's literally how you explain what you do to the man in the street ... we see a lot of applications with an awful lot of Latin in, or very detailed information about the statistical analysis..." (DP2)
Timelines	"Time. Time. Time. It is almost impossible to even roughly estimate a timeframe for a project using routinely collected data. Information Governance approvals, data sharing agreements, and data transfer are all areas in which the researcher has no direct control over timeframe." (RS58) "And that's one of our challenges that we face, where we'd receive an application form in, and [a researcher says] 'I need my data in two weeks' time'. You say well sorry but it takes two weeks to create and curate the data, never mind to get it through the governance process." (DP1) So it's about engaging with us as a data sharing team at the earliest opportunity. You know, there's some fantastic research ideas out there, and some fantastic people who want to do this research. But pressures of actually getting the data in a timely manner, you know, and talking to us first, and saying "I want to do this research, from your experience do you think it would be something that [data provider] could help with? How long might it take to get that data?" But also about, not assuming you can automatically have the data. It's not a given that you can have our data (DP3)
Changes and amendments	"It could be, we see this commonly with section 251, people go and get section 251 support, and then we're actually not happy with the methodology, because it involves us flowing more data than is actually needed to. Or sometimes receiving a huge amount of data from a third party, such as an auditor or a register to link, whereas actually all we need is the identifying data, we don't need the clinical data, and then we can provide a bridge file. So if we can liaise on things like methodology at the earliest point, we can address a lot of those issues." (DP2)
Future-proofing the application	"I think consent as a concept changes over time and some of it can be handled on best intent at the time of collection of consent. But there are hard and fast rules that people can't get around now with things like DPA, GDPR things like that so it's just having that knowledge and being aware that when you are starting to collect data or when you want to start using it for research purposes, do you do things with best intent? Do you consult with the relevant data providers or whoever they are to get it as close as possible to correct?" (DP1) "A lot of the studies are follow-up studies, so whilst they may have been having access to health records during that period, after a certain amount of years they're then going to come into us to follow them up, to have the data. And it's then that the consent model is a lot out of date, and it just doesn't meet today's standards or requirements. And that's a big issue... It's making that decision as well as whether, if there's enough for it to stand as to meet the common law of duty, or whether you would then have to go and get section 251. And I think for some of our researchers that can be seen as... another obstruction, but it's not, it has to meet, you know, it's a legal requirement that you do have to have a legal basis to be able to have access to that". (DP2)
Training for researchers	"The aim with the [guidance documents] is to firstly improve transparency with our customer base, so that they can understand this is what this part of the application form has to adhere to in order to meet the approval standard." (DP2) "we offer a service where if people want a telephone call to discuss their application, or discuss the requirements of their data share, we're quite happy to speak to people. Or if people want a hand filling in the application form, we'll also talk through application processes" (DP3) "what we've done is we've written a guidance document, made that available within our environment for people to refer to. But you can lead a horse to water, but you can't always get it to drink the water." (DP4) "the amount of organisations that don't read the guidance that we put out." (DP3)