**File B – Topic guide for cognitive debriefing**

1. **Documents given to participants**

Participants will be sent in advance, either by email or post, the following:

* Invitation letter for face validity study v2.1 (either adult or parent/guardian version)
* Information sheet for face validity study v2.1 (either adult or parent/guardian version)
* Face validity consent form v2.1 (either adult or parent/guardian version)
* GP letter for face validity exercise v2.1 (either adult or parent/guardian version)
* Background details form v1.1 (if applicable, i.e. for caregivers, clinicians, and/or patients who have not yet completed one if necessary via the NHS trusts)
* Draft DMD-QoL v1.2 (proxy or self-report version)

1. **Before the interview:**

* The interviewer will (re-)introduce themselves, and thank you for agreeing to take part.
* They will provide some background to the research (tailored to the participant):

*“This study is funded by the Charity Duchenne UK and is being carried out by the University of Sheffield. The aim of the project this study is a part of is to develop a new questionnaire for assessing quality of life in boys and men with Duchenne, aged seven and above. We have spoken to a number of boys and men with Duchenne and used that information to produce some draft questions for that questionnaire. With your help, we would like to go through these draft questions in this study, to see if they make sense to you, to see which questions you prefer, and to see if there is anything important to you that we has not been included. We are asking boys and men with Duchenne, their parents/carers, and healthcare professionals to help us with this.”*

* The interviewer will go through some important points with you:
  + We will not be recording this interview, but the researcher will be taking anonymised notes, so we can use these to help improve the draft questionnaire.
  + Everything you say is confidential. Information you share in this interview will not be passed on to others outside of the research team, except if it is information that suggests you may be a threat to yourself or others, which we have a duty to report.
  + When looking at the questionnaire, we might cover questions that you find difficult. You do not have to answer any questions you do not want to. If there are any questions that you are uncomfortable with, or you find difficult, we can move on, so please don’t worry.
  + The interview will take about half an hour to complete. However, you can stop the interview at any time, or take a break, if you wish to do so.
  + We would like to conduct the interview with you personally to hear all of your own views on the issues we discuss. However, it is up to you whether you take part in the interview alone, or with someone else present. We want to feel comfortable and for the interview to fit-in practically with your daily life. If you do decide to have someone with you in the interview, they will not be able to take part in the interview directly, as we are interested in your personal views.
* The interviewer will provide a further copy of the information sheet, and, if you have not done so already, ask you to complete a consent form and for you to complete a form with some background details about you.
* The interviewer will ask you if there is anything you would like to ask us before we begin.
* If you have not done so already, the interviewer will ask you to complete a brief background details form. This is so we can describe on aggregate the kinds of people we have spoken to.

1. **During the interview:**

* Thank you – we’ll now move onto looking at some of the questions for the new questionnaire (refer to document Draft DMD-QoL v1.2). We will be looking over questions that we are thinking about possibly including in our future questionnaire that measures Quality of Life in Duchenne. They come from interviews with boys and men with Duchenne.
* We have grouped these questions into ones that are similar, and they are on the different pages of the document you received.
* For some questions, we want to ask you to consider different ways we could ask the same question, to see which one you prefer. The questions that are asking the same thing in a different way have the same coloured background.
* While you are welcome to answer the questions, we are most interested in your views of the question itself. For example:
  + What you are thinking when you read the question?
  + Whether it is easy to answer
  + That you don’t mind answering the question – that it’s not upsetting or annoying
  + Any other comments you may have about the question
* There are no right or wrong answers – your opinion is important to us.
* We will get through as many questions as we can in the next 30 minutes, but it does not matter if we do not get through them all.

***Questions for participants***

*[depending on the interview it may not be necessary to ask all the questions, it may also be necessary to ask some more probing questions (such as “can you tell me why”. Whenever possible, participants should be allowed to speak spontaneously before probes are offered. If participants are struggling to answer a question then move on - e.g. “we might come back to that later” ]*

* Let’s look at the first page, can you please read the first three sentences (instructions) at the top of the page, and the example question in the top box. Do they make sense to you? Would you understand what you have to do in the questionnaire?
* Consider the responses you can give to the questions: “never”, “sometimes”, “a lot of the time”, “all of the time” – do they make sense to you? Would you agree with the order that they are in? Can you tell the difference between them?
* The questions ask about the last week – do you think that is okay? Why or why not? Can you remember over the last week? Would you prefer a different time period?

[Asking about individual questions (repeat for all questions)]

* Thank you, let’s start with question (1) on the first page. It says that … [read out question – starting with “In the last week…”]
  + What do you think of that question?
  + Would you be able to read it easily? [prompt – are any words difficult?]
  + Would you be able to answer it using the options provided (i.e. never, sometimes, a lot of the time, or all of the time)?
  + Is it okay to answer that question? [prompt – it doesn’t make you too upset?]
  + What do you think that question is asking about? [prompt – what would you be thinking about when you were answering that question?]
  + Does this question make sense when asking about the last week?
  + Do you have any other comments on that question?

[Asking about grouped questions (repeat for grouped questions)]

* Thank you, let’s move on to the next few questions. Here you can see that they have a blue [orange] background, this means that we think that these questions (2), (3), and (4) ask about the same thing in different ways.
  + Ask questions above (for individual questions)
  + [Ask if not clearly obvious questions are asking the same thing] Do you think these questions are asking the same thing? Why or why not?
  + Which of these do you prefer? Why is that?
  + Do you think there is a better way we could ask about this?
* [Ask if relevant] Thank you, of the questions we have talked about today, if they were put in a questionnaire, is there any order you would prefer them to be in? Are there any you would prefer to start or end with? [prompt – for example, we could ask about social participation first, or start or end with more positively worded questions]
* Thank you, apart from the questions that we have looked at today, are there any other aspects of quality of life in Duchenne that you think the questionnaire is missing?

***Useful prompts:***

If respondent can’t think of a reason to support their preference – say something reassuring like “that’s OK sometimes it’s hard to say why we just know which one we like best”

If respondent refers to how an item might make other people feel – say something like “OK thank you – but how does it make you feel – or would it make you personally feel like that?”

1. **Close:**

That’s the end of the interview. Thanks for your contribution it is very much appreciated. The interviewer will ask you if you have any questions about the project. They will explain the next stages of the project, and ask for your consent to be contacted again. They will then thank you for your time.