

GP NOTIFICATION LETTER
Principal Investigator: <insert details>

Recording information on the management of Spinal Muscular Atrophy in the UK – SMA REACH UK Database

 in association with the Neuromuscular Clinical UK Network

Dear Dr …………………………

Patient name………………………………………… D.O.B……………………………..

We have obtained signed consent for the patient named above, registered with your practice, to collect information on a set of functional outcome measures for children and young adults with SMA and record clinical information into a database specially designed for use in the hospitals participating in the UK Neuromuscular Clinical Network (NMCN) and more specifically the SMA REACH UK Database.

Furthermore, patients enrolled in the nusinersen (SPINRAZA®) MAA will have their personal pseudo-anonymised data from the SMA REACH database shared with the following institutions:

* NHS England- To monitor patients treatment start and stop criteria as per the terms of the managed access agreement. To monitor case ascertainment in the SMA REACH database.
* The National Institute of Health and Care Excellence- To ensure compliance with the data collection terms of the managed access agreement i.e. to monitor data completeness of mandatory data fields. To monitor case ascertainment in the SMA REACH database.
* University of Strathclyde- To allow matching of clinical and PROMS data.
* Biogen (the company that makes SPINRAZA®)- To enable the company to analyse the clinical and cost effectiveness of the technology and present a submission of the evidence to NICE for a health technology appraisal.

This is not an exhaustive list and it may be necessary during the course of the MAA to share patient data with other institutions but this data will always be pseudo-anonymised before it is shared.

I have enclosed a copy of the participant information sheet that was given to the person with parental responsibility for the patient. Both they and the patient are aware that they can withdraw from the study at anytime without giving a reason.

Participation in the study should not generate any work within the practice.

If you require any further information about the study please do not hesitate to contact Dr <insert details> or Research Physiotherapist <insert details>.

Or visit the website www.SMAREACHUK.org

Yours Sincerely

……………………………………. (Investigator to sign)