



10 June 2024

Dear Duchenne patient community leaders,

In response to your request to be informed about our efforts in Duchenne we are pleased to introduce a new study that expands our research efforts in DMD. Beyond, and separate from, our gene therapy efforts, Roche is initiating a bone health study that we hope will add to future options for families living with DMD.

This study was developed in response to DMD community feedback about the major impact of fractures and osteoporosis as well as the need for better treatment or prevention options related to bone health. Understanding the negative effect of inflammation on bone health, Roche scientists did preliminary testing to see if satralizumab, a Roche anti-inflammatory medicine, might improve bone strength to reduce fractures. Importantly, our scientists used samples donated and preserved from a previous DMD clinical trial (SPITFIRE; NCT03039686) to run laboratory tests. The analysis showed positive results that led to the development of the **SHIELD DMD** study (NCT06450639), a phase II open-label study to investigate the use of satralizumab in ambulatory and non-ambulatory boys with Duchenne.

Satralizumab is a biologic therapy designed to block interleukin-6 (IL-6) signalling by binding to the IL-6 receptor. It is approved in over 90 countries as a monthly at-home injection for adults and adolescents with a rare condition called neuromyelitis optica spectrum disorder (NMOSD). Satralizumab is being investigated in various other conditions.

In DMD the IL-6 pathway promotes inflammation in the muscles and contributes to bone erosion, loss and fractures. The **SHIELD DMD** study will investigate whether satralizumab can slow bone loss and muscle atrophy to help prevent fractures and improve bone and muscle strength. The study will last 2 years and aims to enrol about 50 individuals aged 8 to 15. Approximately 16 sites are planned in the US, Italy, Poland and Spain. We expect to start enrolling participants in late summer 2024. Site locations will be posted on [clinicaltrials.gov](https://clinicaltrials.gov) when they are open for enrollment.

Families in countries where there are study sites who are interested in participating should speak to their treating physician.

We would like to express our gratitude to the various community members and experts in bone health and DMD that helped shape this trial and the clinical trial participants past and present who are helping to advance research.

We look forward to providing you with updates in the near future, and we thank you for your continued partnership.

Sincerely,

A handwritten signature in black ink that reads "S Blum".

Sandra Blum, on behalf of the Roche DMD team  
Global Patient Partnership Leader

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