

# THE 6-MINUTE WALK TEST AND OTHER CLINICAL ENDPOINTS IN DUCHENNE MUSCULAR DYSTROPHY: RELIABILITY, CONCURRENT VALIDITY, AND MINIMAL CLINICALLY IMPORTANT DIFFERENCES FROM A MULTICENTER STUDY

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**ABSTRACT:** Introduction: An international clinical trial enrolled 174 ambulatory males  $\geq 5$  years old with nonsense mutation Duchenne muscular dystrophy (nmDMD). Pretreatment data provide insight into reliability, concurrent validity, and minimal clinically important differences (MCIDs) of the 6-minute walk test (6MWT) and other endpoints. Methods: Screening and baseline

evaluations included the 6-minute walk distance (6MWD), timed function tests (TFTs), quantitative strength by myometry, the PedsQL heart rate–determined energy expenditure index, and other exploratory endpoints. Results: The 6MWT proved feasible and reliable in a multicenter context. Concurrent validity with other endpoints was excellent. The MCID for 6MWD was 28.5 and 31.7 meters based on 2 statistical distribution methods. Conclusions: The ratio of MCID to baseline mean is lower for 6MWD than for other endpoints. The 6MWD is an optimal primary endpoint for Duchenne muscular dystrophy (DMD) clinical trials that are focused therapeutically on preservation of ambulation and slowing of disease progression.

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**Abbreviations:** 6MWD, 6-minute walk distance; 6MWT, 6-minute walk test; ACS, American Thoracic Society; CNGR, Cooperative International Neuromuscular Research Group; CK, creatine kinase; DMD, Duchenne muscular dystrophy; EEI, energy expenditure index; HRQL, health-related quality of life; MCID, minimal clinically important difference; MPS, mucopolysaccharidosis; nmDMD, nonsense mutation DMD; NSAA, North Star Ambulatory Assessment; PedsQL, Pediatric Quality of Life Inventory; TFT, timed function test

**Key words:** 6-minute walk test; ambulation; Duchenne muscular dystrophy; energy expenditure index; muscular dystrophy; myometry; natural history; PedsQL; timed function test

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Additional Supporting Information may be found in the online version of this article.

\*Collaborating authors are listed in Appendix 1. Other members of the PTC124-GD-007-DMD Study Group are listed in Appendix 2 in the Supporting Information.

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Reliability, Validity and MCID of 6MWT and other Endpoints in DMD

Duchenne muscular dystrophy (DMD) is a disabling and life-threatening X-linked genetic disorder caused by defects in the gene for dystrophin, a protein that stabilizes muscle cell membranes.<sup>1</sup> DMD is characterized by complete loss of dystrophin and is the most common neuromuscular disease of childhood. It affects 1 in 3800–6300 males, and there are an estimated 15,000 patients with the disease in the USA.<sup>2,3</sup> There is no approved therapy that addresses the underlying cause of DMD.<sup>4,5</sup> In  $\sim 13\%$  of boys with nonsense mutation DMD (nmDMD), which represents  $\sim 1700$  boys in the USA and  $\sim 2400$  boys in Europe), the causative defect in the dystrophin gene is a nonsense mutation that truncates dystrophin protein production by introducing a premature stop codon into dystrophin mRNA.<sup>6–8</sup>

## THE NEED FOR CLINICALLY MEANINGFUL ENDPOINTS IN DMD

Given that several novel approaches to treatment of DMD have shown promise in preclinical and/or proof-of-concept clinical studies,<sup>9–12</sup> the research community has faced the need to identify and develop clinically meaningful outcome measures for use in pivotal therapeutic trials. In boys with DMD, walking abnormalities are a major disease manifestation that has great importance to patients and

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children some interesting facts about orcas while they listen

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web the teacher made powerpoint guides pupils through the report writing process it s great for ensuring understanding before encouraging children to have a go themselves this report writing checklist makes a great activity for helping them evaluate after writing but can also help prepare ks2 for this planning stage

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web the powerpoint is full of fantastic ideas to help your class think of great ways of report writing there are loads of tips to help make writing interesting and ideas for places to find reliable information the presentation comes with a super handy worksheet designed to get children to think about sources

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web jan 6 2022 take the information from your graphic organizer and turn it into essay format typically your report will be five paragraphs as follows introduction main idea 1 main idea 2 main idea 3

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web teach children how to write an effective report with this template and powerpoint pack you can use this how to write a report template and powerpoint to introduce your year 3 6 students to the purpose structure and process of writing reports plus it includes lots of ideas to help your class think of great ways of report writing

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web this powerpoint presentation includes 8 themed prompts from which students can choose a specific subject to write about each of the prompt slides also includes some thinking points for students to consider and use to help structure their information report

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web this powerpoint presentation has been designed to teach your students about the text structure and language features of informative writing it addresses the following content an overview of the purpose and types of informative texts

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web to meet the purpose of the information report the writer can make certain language choices these choices can be highlighted and made explicit to the students see example language features docx 24 54kb note not every word or choice needs to be highlighted for example in the mentor text there are many nouns

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web this powerpoint is a helpful tool to teach the use of spidergrams when organising and locating information before writing an information report if you d like to encourage children to assess their own report work have a look at our report writing

checklist

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web from the first research project in grade school to more complex reports assigned in middle or high school report writing is a process that some students struggle to master whether it s about a book historical topic scientific inquiry activity or another type of report students can divide the assignment into

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web for example this report writing frame is a great starting point for kids who need a bit of structure to support them while writing their first report it s a report template with spaces for the report title introduction a couple of subheadings and space for a picture or diagram

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