Motor function assessments in DMD

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assessments in DMD.

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Motor function assessments in DMD

Functional assessments in DMD

NSAA, 6MWT, 4SC, and SV95C are all motor function assessments that are commonly used as primary and/or secondary endpoints in clinical trials in ambulatory individuals with DMD.[1–4]

Specialized functional assessments and timed tests are used to standardize the evaluation of motor function in individuals with DMD. They are important both in monitoring disease progression and assessing treatment efficacy.[2,5]

While many tests are used to assess motor function in ambulatory individuals, fewer are designed to assess upper body function in non-ambulatory individuals.[2,5]

Commonly used assessments[1–4,6–8]

Ambulatory individuals	Non-ambulatory individuals

• 6MWT
• NSAA
• Timed function tests:
  ▪ 10MRW
  ▪ TTR
  ▪ 4SC
• SV95C
• MFMS
	• PUL
	• Brooke Upper Extremity Scale
	• MFMS

MORE ON 6MWT, NSAA, 10MRW, TTR, AND 4SC

4SC, 4-stair climb; **6MWT**, 6-minute walk test; **10MRW**, 10-meter run/walk; **DMD**, Duchenne muscular dystrophy; **EMA**, European Medicines Agency; **MFMS**, Motor Function Measure Scale; **NSAA**, North Star Ambulatory Assessment; **PUL**, performance of upper limb; **SV95C**, stride velocity 95th centile; **TTR**, time to rise.

References: 1. EMA Qualification Opinion. July 2023. https://www.ema.europa.eu/en/documents/scientific-guideline/qualification-opinion-stride-velocity-95th-centile-primary-endpoint-studies-ambulatory-duchenne-muscular-dystrophy-studies_en.pdf Accessed January 13, 2025; 2. EMA. Guideline on the clinical investigation of medicinal products for the treatment of Duchenne and Becker muscular dystrophy. 2016. https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-clinical-investigation-medicinal-products-treatment-duchenne-and-becker-muscular-dystrophy_en.pdf Accessed January 13, 2025; 3. Mercuri E, et al. *Lancet Neurol.* 2024;23(4):393–403; 4. Mendell JR, et al. *Nat Med*. 2025;31(1):332–41; 5. Birnkrant DJ, et al. *Lancet Neurol.* 2018;17(3):251–67; 6. ClinicalTrials.gov/NCT05185622 Accessed February 7, 2025; 7. ClinicalTrials.gov/NCT02525302 Accessed February 7, 2025; 8. Muntoni F, et al. Poster presentation at the World Muscle Society Annual Congress, Charleston, South Carolina, USA, October 3–7, 2023. Poster 47.

Motor function assessments in DMD

Characteristics of SV95C

SV95C is a digital ambulation measure derived from a wearable device that allows the passive collection of continuous and objective data in real-world settings.

It is the first digital measure to receive qualification from a regulatory body (EMA) for use as a primary endpoint in studies of boys with DMD ≥4 years of age.[1–3] SV95C is highly correlated to 6MWT, one of the most commonly used endpoints in studies in ambulatory DMD. However, SV95C has greater sensitivity than other motor function tests, meaning that it is able to detect disease progression earlier.[2,3] SV95C has demonstrated sensitivity to detect change in individuals with DMD over time in natural history studies, steroid-treated individuals, and in clinical trials.[3]

Digital endpoints such as SV95C may provide a more accurate representation of an individual's mobility versus established DMD clinical outcome assessments including 6MWT, 4SC, and NSAA, which can be affected by external factors that impact assessment reliability and provide only a snapshot of their maximal functional ability at a specific point in time.[1–3]

Factors that can affect the reliability of clinic-based functional assessments in DMD

Person-specific factors[1,2]
- Mood/motivation
- Fatigue
- Concentration
- Wellbeing
- Growth
- Intellectual maturation/ability

Environmental/social factors[3]
- Time of day
- Burden of travelling to clinics
- Artificial (clinic) setting

MORE ON 6MWT, NSAA, 10MRW, TTR, AND 4SC

4SC, 4-stair climb; **6MWT**, 6-minute walk test; **DMD**, Duchenne muscular dystrophy; **EMA**, European Medicines Agency; **NSAA**, North Star Ambulatory Assessment; **SV95C**, stride velocity 95th centile.

References: 1. Servais L, et al. *Nat Med.* 2023;29(10):2391–2; 2. Servais L, et al. *Sci Rep.* 2024;14(1):29681; 3. EMA Qualification Opinion. July 2023. https://www.ema.europa.eu/en/documents/scientific-guideline/qualification-opinion-stride-velocity-95th-centile-primary-endpoint-studies-ambulatory-duchenne-muscular-dystrophy-studies_en.pdf Accessed January 13, 2025.

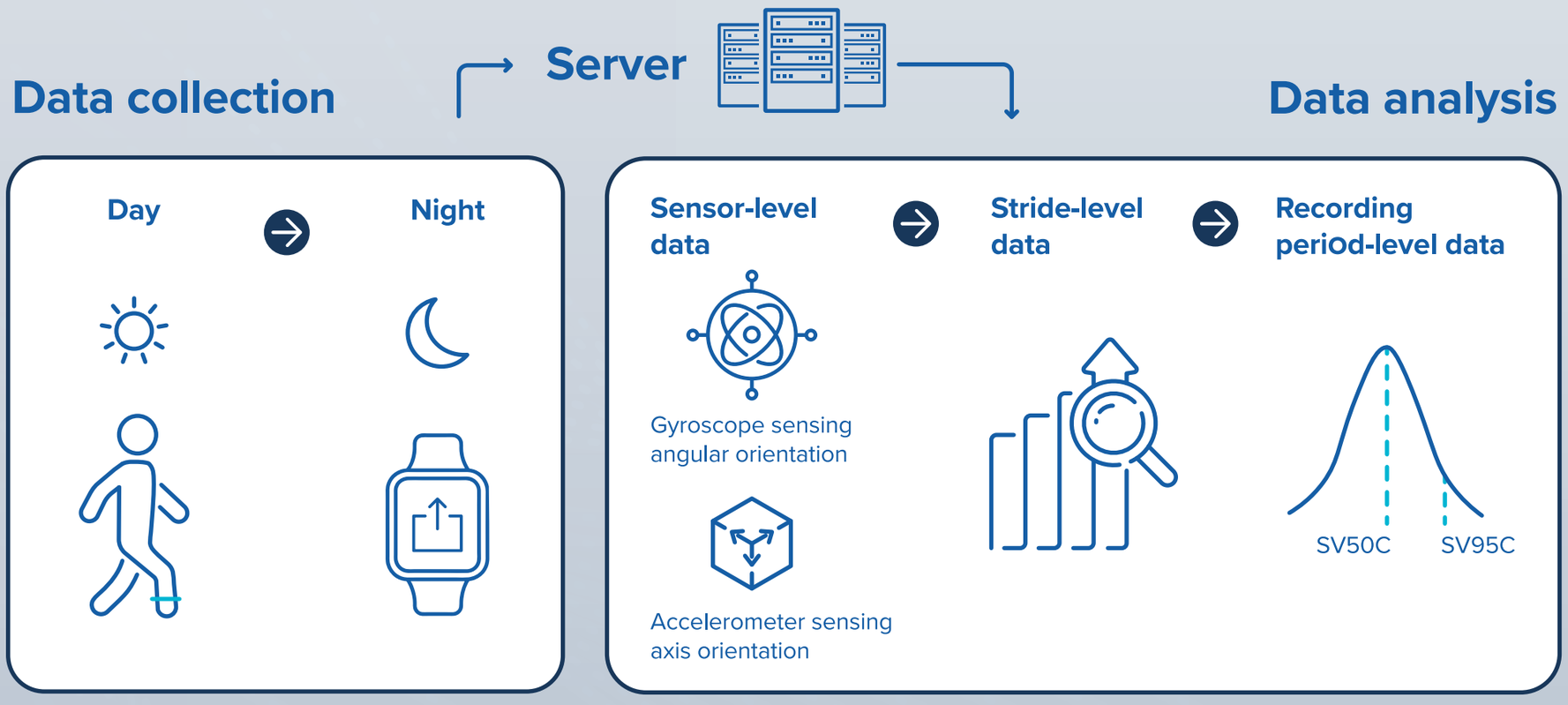
Motor function assessments in DMD

SV95C – Measurement and methodology

SV95C represents the speed of the fastest 5% of strides taken during everyday living – i.e, the threshold at which 95% of strides are slower and 5% are faster.[1,2]

An ankle-worn digital device (that meets technical specifications set out by the EMA) passively collects raw sensor data continuously throughout the day over a defined recording duration (minimum 50 hours, optimum 180 hours). Data are then uploaded to a server and processed to obtain SV95C from stride-level data (stride length and stride speed).[1,2]

The proposed **minimal clinically important difference (MCID)*** of SV95C is estimated to be 0.1 m/s (36 m in 6 min) which corresponds to a 6MWT MCID of 30 m.[2–5] **(TAP FOR DEFINITION)**



MORE ON 6MWT, NSAA, 10MRW, TTR, AND 4SC

*Distribution-based threshold.

6MWT, 6-minute walk test; **EMA**, European Medicines Agency; **m**, meter; **m/s**, meters per second; **SV95C**, stride velocity 95th centile.

References: 1. Servais L, et al. *Nat Med.* 2023;29(10):2391–2; 2. Servais L, et al. *Sci Rep.* 2024;14(1):29681; 3. EMA Qualification Opinion. July 2023. https://www.ema.europa.eu/en/documents/scientific-guideline/qualification-opinion-stride-velocity-95th-centile-primary-endpoint-studies-ambulatory-duchenne-muscular-dystrophy-studies_en.pdf Accessed January 13, 2025; 4. McDonald CM, et al. *Muscle Nerve.* 2013;48(3):357–68; 5. EMA Qualification Opinion. April 2019. https://www.ema.europa.eu/en/documents/scientific-guideline/qualification-opinion-stride-velocity-95th-centile-secondary-endpoint-duchenne-muscular-dystrophy-measured-valid-and-suitable-wearable-device_en.pdf Accessed January 13, 2025.

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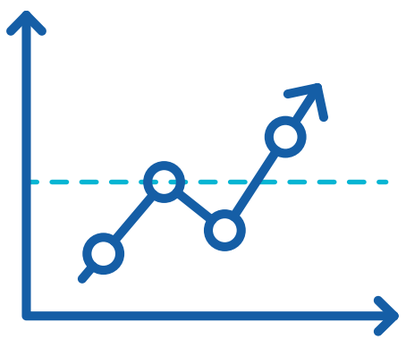


Minimal clinically important difference (MCID) is used to assess change in clinical presentation and may be used to determine response to treatment or disease progression.

Reference
Duong T, et al. *J Neuromuscul Dis.* 2021;8(6):939–48.

Accelerometer sensing
axis orientation

MORE ON 6MWT, NSAA, 10MRW, TTR, AND 4SC

6MWT, 6-minute walk test; **EMA**, European Medicines Agency; **m**, meter; **m/s**, meters per second; **SV95C**, Stride Velocity 95th Centile.

References: 1. Servais L, et al. *Nat Med.* 2023;29(10):2391–92; 2. Servais L, et al. *Sci Rep.* 2024;14(1):29681; 3. EMA Qualification Opinion. July 2023. https://www.ema.europa.eu/en/documents/scientific-guideline/qualification-opinion-stride-velocity-95th-centile-primary-endpoint-studies-ambulatory-duchenne-muscular-dystrophy-studies_en.pdf Accessed January 13, 2025; 4. McDonald CM, et al. *Muscle Nerve.* 2013;48(3):357–68; 5. EMA Qualification Opinion. April 2019. https://www.ema.europa.eu/en/documents/scientific-guideline/qualification-opinion-stride-velocity-95th-centile-secondary-endpoint-duchenne-muscular-dystrophy-measured-valid-and-suitable-wearable-device_en.pdf Accessed January 13, 2025.

Motor function assessments in DMD

SV95C – Correlation with established measures

Convergent validity reflects the degree to which the score on one clinical outcome measure correlates with scores on other tests that measure the same construct. In an analysis of 107 individuals with DMD, SV95C significantly correlated with 6MWT, NSAA, and 4SC at baseline and at follow-up over 12 months (table).[1]

Spearman's correlation coefficients between absolute value of SV95C and established COAs in individuals with DMD[2]

	Baseline (N = 107)	Month 3 (n = 43)	Month 6 (n = 20)	Month 9 (n = 24)	Month 12 (n = 15)
6MWT	0.657**	0.761**	0.524*	0.691**	0.835**
NSAA	0.644**	0.575**	0.396^{ns}	0.677**	0.753**
4SC	−0.634**	−0.603**	−0.536*	−0.651**	−0.749**

*p<0.05; **p<0.01; ns, not significant.

Other measures have also supported the clinical validation of SV95C:

Test-retest reliability: ICC of 0.970 (95% CI: 0.947–0.983) based on two successive SV95C measurements taken 1 month apart in 52 individuals[1,2]

Known-groups validity: Lower median SV95C scores in individuals with DMD (N=125; 1.563 m/s) vs age-matched controls (N=66; 2.713 m/s; p<0.001)[1,2]

MORE ON 6MWT, NSAA, 10MRW, TTR, AND 4SC

4SC, 4-stair climb; **6MWT**, 6-minute walk test; **CI**, confidence interval; **COA**, clinical outcome assessment; **DMD**, Duchenne muscular dystrophy; **ICC**, intraclass correlation coefficient; **NSAA**, North Star Ambulatory Assessment; **SV95C**, stride velocity 95th centile.

References: 1. Servais L, et al. *Sci Rep*. 2024;14(1):29681; 2. EMA Qualification Opinion. July 2023. https://www.ema.europa.eu/en/documents/scientific-guideline/qualification-opinion-stride-velocity-95th-centile-primary-endpoint-studies-ambulatory-duchenne-muscular-dystrophy-studies_en.pdf Accessed January 13, 2025.

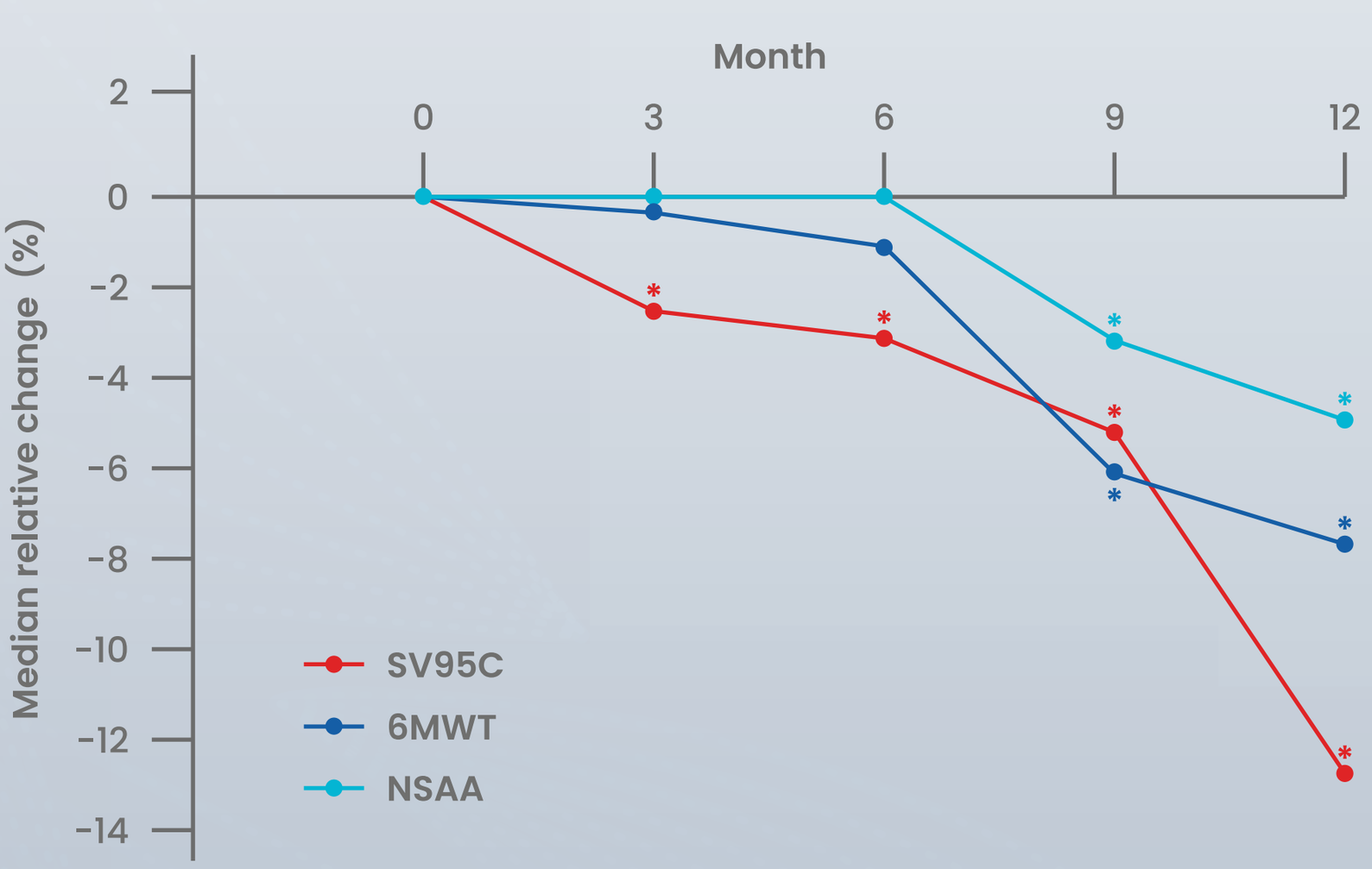
Motor function assessments in DMD

SV95C – Sensitivity and responsiveness

Responsiveness is the ability of a measure to detect change in functional capacity over time. In an analysis of individuals with DMD on stable steroid regimens from three natural history studies and two clinical trials, SV95C demonstrated a progressive loss of maximal speed that could be observed as early as 3 months versus 9 months with 6MWT and NSAA (figure).

These data indicate that SV95C may have a greater sensitivity to 12-month disease progression than established ambulation measures.

Median change from baseline and SRMs for SV95C, 6MWT, and NSAA in individuals with DMD on a stable steroid regimen



Asterisks denote statistically significant changes from baseline
SV95C: 3 months: p=0.0019; 6 months: p=0.0009; 9 months: p=0.0005; 12 months: p=0.0003
6MWD: 9 months: p=0.0016; 12 months: p=0.0007
NSAA: 9 months: p=0.0153; 12 months: p=0.0192

MORE ON 6MWT, NSAA, 10MRW, TTR, AND 4SC

6MWT, 6-minute walk test; **DMD**, Duchenne muscular dystrophy; **NSAA**, North Star Ambulatory Assessment; **SRM**, standardized response mean; **SV95C,** stride velocity 95th centile.

Reference: Servais L, *et al. Sci Rep.* 2024;14(1):29681.

Motor function assessments in DMD

Upper limb function assessments

PUL and the Brooke scale are both clinician-assessed upper limb function measures that can be used to assess ambulatory and non-ambulatory individuals with DMD.[1,2]

The Brooke scale provides a quick and easy method of functional classification; however, it is less comprehensive than PUL. The entry task in PUL is based on the Brooke scale.[1,2]

PUL and the Brooke scale have both been shown to correlate with pulmonary function measures.[3,4] Monitoring pulmonary function is particularly important in DMD as cardio-pulmonary complications are a predominant cause of early morbidity and mortality.[3]

PUL[1]	Brooke scale[2]
Detailed assessment of multiple tasks relating to everyday life **22 tasks (total score 42)**  Scores range from 0–6, 0–2, or 0–1 for each task, with higher score indicating greater function	Simple test with a single overall grade **Grade range: 1–6** **1:** Can raise straight arms above head **2:** Can raise arms above head (flexing elbow) **3:** Cannot raise arms above head but can raise glass to mouth **4:** Cannot raise glass but can raise hands to mouth **5:** Cannot raise hands to mouth but can pick up a pen or hold coins **6:** Cannot raise arms and no hand function

MORE ON 6MWT, NSAA, 10MRW, TTR, AND 4SC

DMD, Duchenne muscular dystrophy; **NSAA**, North Star Ambulatory Assessment; **PUL**, performance of upper limb.

References: 1. Mayhew AG, et al. *Dev Med Child Neurol.* 2020;62(5):633–9; 2. Lu YM, Lue YJ. Strength and Functional Measurement for Patients with Muscular Dystrophy. In: Hegde M, Ankala A, eds. *Muscular Dystrophy* [Internet]. IntechOpen; 2012. https://www.intechopen.com/chapters/36741 Accessed January 8, 2025; 3. Mayer OH, et al. *US Neurology*. 2017;13(1):35–41; 4. Lee HN, et al. *Neuromuscul Disord.* 2016;26(4-5):264–71.

Motor function
assessments in DMD

Tap to learn more about some of the other motor function assessments that have been commonly used in DMD:

- 6-minute walk test (6MWT)
- 10-meter run/walk (10MRW)
- Time to rise (TTR)
- 4-stair climb (4SC)
- North Star Ambulatory Assessment (NSAA)

- Functional assessments in DMD
- Characteristics of SV95C
- SV95C – Measurement and methodology
- SV95C – Correlation with established measures
- SV95C – Sensitivity and responsiveness
- Upper limb function assessments

Motor function assessments in DMD

Tap to learn more about some of the other motor function assessments that have been commonly used in DMD:

6-minute walk test (6MWT)

6-minute walk test (6MWT)

The distance an individual can walk in 6 minutes.[1]

Cut-off associated with loss of ambulation at 48 weeks
<325 meters[*2]

BACK

*Longitudinal multicenter natural history data from 57 individuals with DMD aged 5–15 years over 48 weeks.[2]

DMD, Duchenne muscular dystrophy.

References: 1. Arora H, et al. *Muscle Nerve*. 2018;58(5):631–8;
2. McDonald CM, et al. *Muscle Nerve*. 2013;48(3):343–56.

SV95C – Measurement and methodology

SV95C – Correlation with established measures

SV95C – Sensitivity and responsiveness

Upper limb function assessments

Date of preparation: July 2026. MED-00697.

Motor function assessments in DMD

Tap to learn more about some of the other motor function assessments that have been commonly used in DMD:

6-minute walk test (6MWT)

10-meter run/walk (10MRW)

The time taken for an individual to run or walk 10 meters.

Cut off for predicting loss of function over 1 year:
>7.6 seconds (95% CI: 7.6–9.2)*

BACK

*Longitudinal, multicenter study in 92 individuals with DMD aged 5–12.9 years over 1 year.

CI, confidence interval; **DMD**, Duchenne muscular dystrophy.

Reference: Arora H, *et al. Muscle Nerve.* 2018;58(5):631–8.

SV95C – Measurement and methodology

SV95C – Correlation with established measures

SV95C – Sensitivity and responsiveness

Upper limb function assessments

Date of preparation: July 2026. MED-00697.

Motor function assessments in DMD

Tap to learn more about some of the other motor function assessments that have been commonly used in DMD:

Time to rise (TTR)

The time taken to stand from lying face up on the ground.[1]

Cut-off for predicting functional decline:
≥5 seconds[*1]

Cut-off for predicting loss of ambulation within 2 years:
≥10 seconds[*1]

Median age at loss of ability to complete TTR:
11.6 years
(SE; 95% CI: 0.3; 11.1–12.3)[†1]

BACK

*Longitudinal, multicenter study in 340 individuals with DMD aged 2–28 years;[2]

†Prospective, multicenter study in 440 individuals with DMD aged 2–28 years. Age at loss of ambulation based on 207 individuals with ≥1 year corticosteroid treatment.[1]

CI, confidence interval; **DMD**, Duchenne muscular dystrophy; **SE**, standard error.

References: 1. McDonald CM, et al. *Lancet.* 2018;391(10119):451–61;
2. McDonald CM, et al. *Neuromusc Disord.* 2013;23:752.

SV95C – Sensitivity and responsiveness

Upper limb function assessments

Date of preparation: July 2026. MED-00697.

Motor function assessments in DMD

Tap to learn more about some of the other motor function assessments that have been commonly used in DMD:

4-stair climb (4SC)

The time taken for an individual to climb four stairs.[1]

Cut-off for predicting loss of function over 1 year: **>6.2 seconds (95% CI: 4.5–7.4)**[*1]

Median age at loss of ability to complete 4SC: **13.2 years (SE; 95% CI: 0.4; 12.4–14.1)**[†2]

BACK

*Longitudinal, multicenter study in 92 individuals with DMD aged 5–12.9 years;[1]

†Prospective, multicenter study in 440 individuals with DMD aged 2–28 years. Age at loss of ambulation based on 225 individuals with ≥1 year corticosteroid treatment.[2]

CI, confidence interval; **DMD**, Duchenne muscular dystrophy; **SE**, standard error.

References: 1. Arora H, et al. *Muscle Nerve.* 2018;58(5):631–8;
2. McDonald CM, et al. *Lancet.* 2018;391(10119):451–61.

SV95C – Correlation with established measures

SV95C – Sensitivity and responsiveness

Upper limb function assessments

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Motor function assessments in DMD

Tap to learn more about some of the other motor function assessments that have been

North Star Ambulatory Assessment (NSAA)

The sum of scores on **17 ordinal tasks**, each scored as:[1]
0 = inability to perform task
1 = modified method of completing task, or
2 = normal activity with no obvious modification

Tasks include rising from the floor, moving from sitting to standing, jumping, running, and ascending or descending steps.[1,2]

Younger and older individuals may sometimes have the same NSAA total score but are likely to have a different prognosis, so total score should be interpreted within a trend of decline (e.g., loss of ≥3 points in the last 14 months) or stability/improvement.[1]

Probability of being ambulant when aged ≥13 years:[*3]

Scoring <22: 13% (95% CI: 5–34%)
Scoring 22 to 25: 19% (95% CI: 9–38%)
Scoring 26 to 28: 34% (95% CI: 21–55%)
Scoring 29 to 31: 34% (95% CI: 21–54%)
Scoring 32 to 34: 61% (95% CI: 47–79%)

BACK

*Retrospective, multicenter study in 293 individuals with DMD with a mean age at first visit of 5.5 years.[3]

CI, confidence interval; **DMD**, Duchenne muscular dystrophy.

References: 1. Stimpson G, et al. *Eur J Paediatr Neurol*. 2024:53:123–30;
2. Muntoni F, et al. *PLoS One*. 2019;14(9):e0221097;
3. Zambon AA, et al. *Dev Med Child Neurol*. 2022;64(8):979–88.

Upper limb function assessments

Date of preparation: July 2026. MED-00697.

Motor function assessments in DMD

Tap to learn more about some of the other motor function assessments that have been

Stand
Stand barefoot for as long and still as possible (no external support)

Walk
Walk forward barefoot (long enough to observe gait)

Run
Run as fast as possible for about 10 meters

Ascend step (right and left sides)
Step onto a box (≥15 cm high)

Descend from step (right and left sides)
Step down from the box (≥15 cm high) facing forwards

Stand on heels
Lean back onto heels while barefoot (both feet lifted off ground towards shin)

Stand on leg (right and left sides)
Stand on one leg with arms down for as long as possible

Hop (right and left legs)
Stand on one leg and hop one-legged while barefoot

Jump
Jump as high as possible from standing with both feet together

Sit up from lying down
Lie flat on the floor with arms by side and move to a sitting position (without turning towards the floor or using both hands)

Rise from floor
Lay flat on back and stand up as quickly as possible (without Gower's maneuver)

Lift head
Lay flat on the floor with arms crossed across the chest and lift head, touching chin to chest, while keeping arms folded

Rise from chair
Stand up from a seated position in a chair with arms crossed

touchNEUROLOGY. North Star Ambulatory assessment. https://www.touchneurology.com/wp-content/uploads/sites/3/2018/03/www.musculardystrophyuk.org_assets_0000_6388_NorthStar.pdf Accessed February 24, 2025.

Upper limb function assessments