

# The importance and use of Syde® wearable technology and Stride Velocity 95<sup>th</sup> Centile (SV95C) endpoint in Duchenne muscular dystrophy

P Strijbos\*,<sup>1</sup> M Guridi Ormazabal,<sup>1</sup> J Braid,<sup>2</sup> E Zhuravleva<sup>1</sup>

<sup>1</sup>F. Hoffmann-La Roche Ltd, Basel, Switzerland; <sup>2</sup>Roche Products Ltd, Welwyn Garden City, UK.

\*Presented on behalf of the authors



## What does this research mean for the Duchenne community?

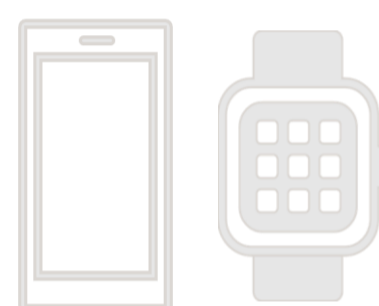
- Validated and suitable wearable technology allows the measurement of functional outcomes such as Stride Velocity 95<sup>th</sup> Centile (SV95C) in clinical trials of Duchenne.
- SV95C can objectively measure functional disease progression, reduce the burden of traditional, in-clinic assessments and improve the experience of individuals participating in clinical trials.

## Conclusions

- In 2019, SV95C was qualified by the EMA for use as secondary endpoint in pivotal studies of Duchenne.
- The development of SV95C highlights the close collaboration and synergy between multiple stakeholders, including patients, caregivers and PAG groups. This partnership can streamline the development of “fit-for-purpose” and real-world use devices and outcomes that balance precision, accuracy, and reliability with user-friendliness for patients.

## What are digital outcome assessments?

- Digital outcome assessments are measures that are collected by means of digital devices.<sup>1</sup>
- Only validated and suitable devices can capture digital outcome assessments with sufficient accuracy and precision to be useful in clinical development.
- Digital outcome assessments may help clinicians understand how an individual with a particular condition such as Duchenne is progressing.<sup>1</sup>



## Why are digital outcome assessments important?

- Clinic-based assessments can be subjective and burdensome, and they only provide a snapshot of an individual’s condition at the time of testing.
- Digital outcome measures can be measured continuously, over prolonged periods of time, providing a more objective and accurate assessment and reducing the burden of in-clinic assessments.<sup>2,3</sup> They also provide a patient-relevant and patient-friendly measure of real world function.



## SV95C\*

- SV95C is a digital outcome measure that represents the fastest 5% of strides taken by the wearer during normal daily living over a period of 180 hours.<sup>2</sup>
- It is the first outcome measure to be qualified for use as a secondary endpoint in clinical trials of Duchenne by a regulatory body, the European Medicines Agency (EMA).<sup>4</sup>
- Several studies in Duchenne use(d) SV95C as a secondary endpoint, including studies of the gene therapy delandistrogene moxeparvovec (EMBARC; Study 301),<sup>5</sup> anti-myostatin RG6206 (SPITFIRE),<sup>6</sup> gene therapy SGT-001 (IGNITE)<sup>7</sup> and oligonucleotide suvodirsén (DYSTANCE 51).<sup>8</sup>



\*SV95C was jointly developed by Sysnav, Prof Laurent Servais (Oxford University) and F. Hoffmann-La Roche.

## Syde®

- Syde® (new form factor of ActiMyo®) is a wearable device specifically developed to record the movements of a person in their normal environment.<sup>2</sup>
- It can record upper and lower limb (i.e. arms and legs) activity in all people with Duchenne.<sup>9</sup>
- Syde® can be used to measure SV95C when the device is worn on the ankle.<sup>2</sup>



## EMBARC study

- The EMBARK study is a Phase 3 clinical trial that evaluates the safety and efficacy of delandistrogene moxeparvovec in people with Duchenne aged 4–7 years who are able to walk.<sup>5</sup>
- Change in SV95C from baseline to Week 52 (measured by Syde®) is a secondary endpoint in this study.

## Acknowledgments

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## Abbreviations

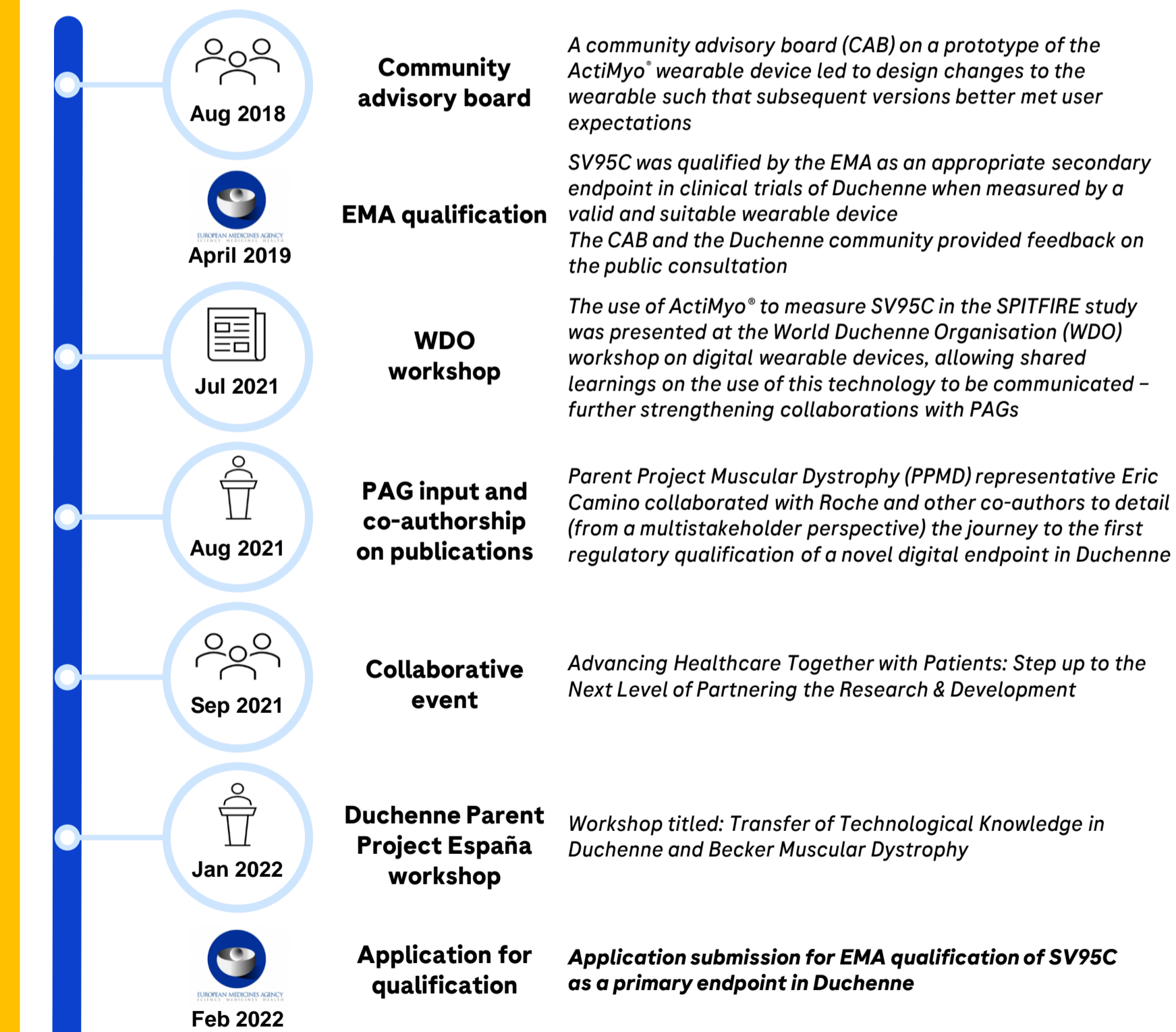
CAB, community advisory board; EMA, European Medicines Agency; PAG, Patient Advocacy Group; PPMD, Parent Project Muscular Dystrophy; SV95C, Stride Velocity 95<sup>th</sup> Centile; WDO, World Duchenne Organisation.

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## SV95C digital endpoint development

- Perspectives of PAG representatives, patients and caregivers were considered during the development of Syde® and SV95C.



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