

An Implantable SCS System With Automatic Daily Remote Monitoring and Remote Programming: First-In-Human Experience



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INTRODUCTION

- Most spinal cord stimulation (SCS) systems require frequent in-person reprogramming to optimize stimulation and promote optimal management of chronic pain:
 - A real-world cross-sectional cohort study found clinic visits were commonly required to address SCS issues and wait times negatively impacted patients^{1,2}
- Recent technological advances in SCS device capabilities have presented the opportunity to provide remote SCS management and support,³ intended to improve patient outcomes via timely identification and resolution of device and therapy-related issues; however, more clinical evidence is needed beyond data from 2 pilot studies³⁻⁵
- To our knowledge, BENEFIT-03 is the world's first long-term study of an SCS system with automatic daily transmission of objective device monitoring data and remote programming capabilities
- In March 2023, the US Food and Drug Administration approved the Prospera™ SCS System* as an aid in the management of chronic, intractable pain in the trunk and/or limbs (BIOTRONIK SE & Co. KG, Berlin, Germany)
 - The system features RESONANCE™, the first and only multiphase stimulation paradigm, paired with proactive care, a patient-centric care model made possible by offering automatic, objective, daily remote monitoring, remote programming, and ongoing management and support

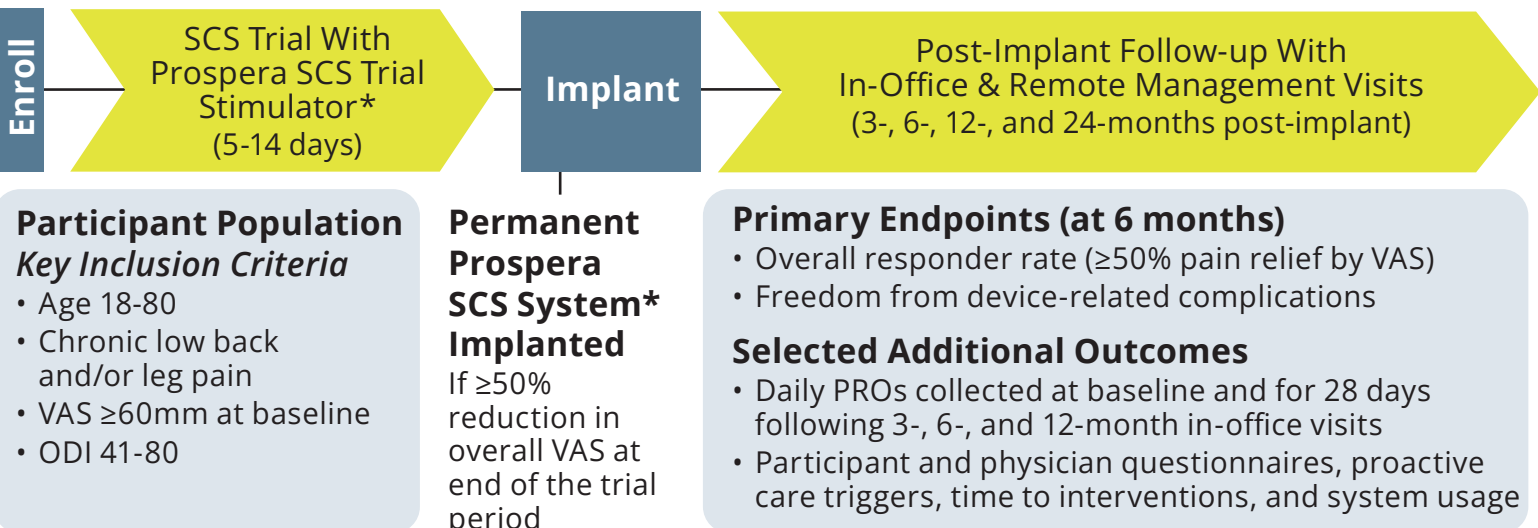
OBJECTIVE

- To report on an interim analysis of remote device management outcomes from BENEFIT-03 (NCT04683718), an ongoing, first-in-human, 2-year study of an implantable SCS system with multiphase stimulation, automatic daily remote monitoring, and remote programming

METHODS

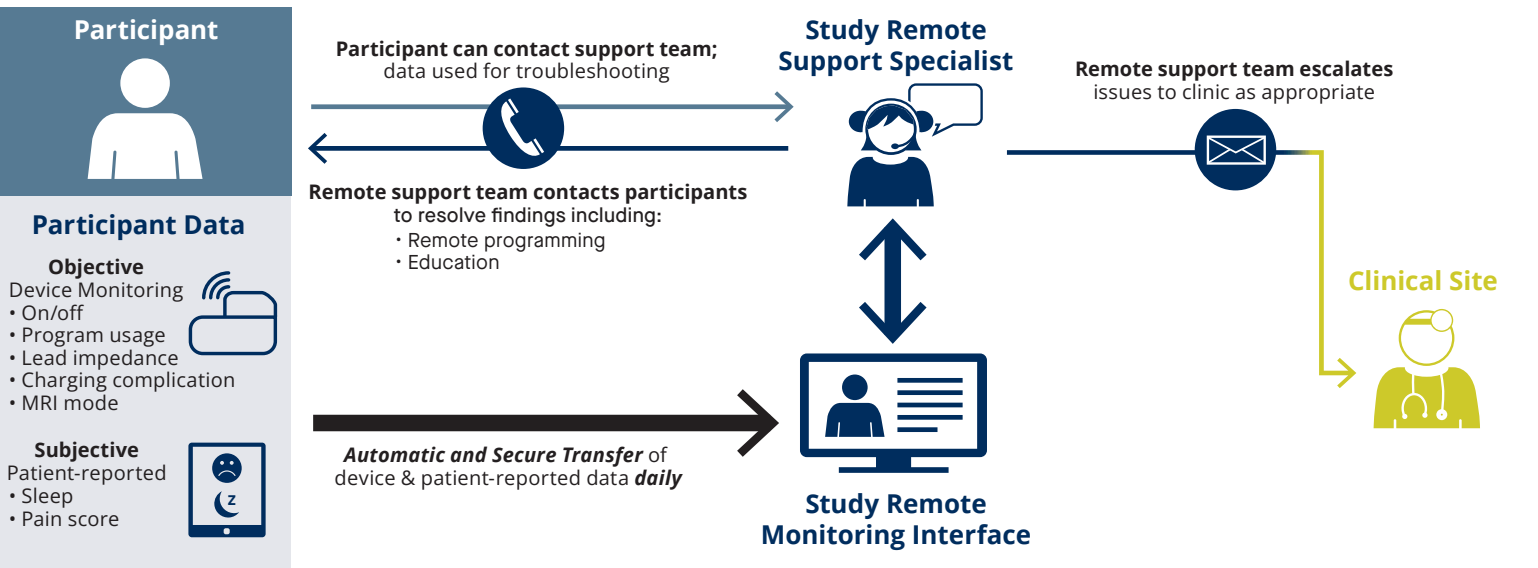
- BENEFIT-03 is a prospective, multicenter, single-arm study with 24-month follow-up conducted at up to 5 Australian sites with Human Research Ethics Committee approval and participant informed consent (Figure 1)
- Remote visits may be initiated by participants, investigators, proactive triggers (based on automatic daily device monitoring), or patient-reported outcomes (PROs) (Figure 2)
- Additional study data are detailed in 2 other ASRA posters presented by L. Kapural

Figure 1. Study Design



ODI, Oswestry Disability Index; PROs, patient reported outcomes; SCS, spinal cord stimulation; VAS, Visual Analog Scale.

Figure 2. Remote Device Management



MRI, magnetic resonance imaging.

INTERIM 6-MONTH RESULTS[†]

Participants and Baseline Characteristics

- From Sept 2021 to Sept 2022, 55 participants were consented and assessed for eligibility; of these, 46 were provisionally enrolled, 34 were trialed, and 31 were implanted with the Prospera SCS System*
- Participants with baseline data (n=46) demonstrated high disease burden: mean pain duration over 10 years; mean overall pain intensity 80.3 by Visual Analog Scale; 50% had previous back surgery; 56.5% were taking opioid analgesics (mean: 42 mg/day morphine equivalent)
- Prior to enrollment, participants had multiple office visits annually for their chronic pain management, resulting in high costs and affecting work (Table 1)

Table 1. Baseline Travel Burden

Last 12 months	n=44 ^a
Number of office visits for pain, mean ^b	16.0
Travel costs per office visit, mean, AUD ^c	\$156.15
Distance from home to clinic, mean, km	130
Travel time from home to clinic, mean, minutes	109
Clinic visits requiring leave/lost wages, n (%) ^d	
Yes	9 (69.2)
No	3 (23.1)
Unknown	1 (7.7)

AUD, Australian dollar; OOP, out of pocket. ^a44 consented participants had data available at time of this interim analysis (June 2023). ^bn=43. ^cn=39. ^dn=13 (full- or part-time employed participants). The number of participants varies due to data availability and the status of the participant outcome.

Remote Device Management

- In this interim analysis, 100 remote device management sessions were conducted to date (Table 2)
- Of 73 sessions to transmit new SCS programs, 71 occurred post-implant to optimize pain management; most (60 sessions) occurred in the first 6-months post implant, presumably for initial dose titration
- Real-time monitoring sessions were typically used to ensure participants were running the intended program and amplitude

Table 2. Remote Device Management Sessions (100 Total)^a

	Number
Sessions transmitted new SCS programs	73
During trial period	2
Post-permanent implant	71
≤6 months post-implant	60
>6 months post-implant	11
Real-time monitoring sessions	27

^aCutoff date: May 2023.

CONCLUSIONS

- Interim analysis of the ongoing BENEFIT-03 study showed remote device management to be a highly useful tool, well received by both SCS participants and their clinicians
- Automatic daily remote device monitoring allowed for rapid, proactive identification of potential SCS device-related issues, which were resolved much faster than standard in-clinic follow-ups¹

Automatic Remote Device Monitoring and Proactive Care

- Study remote management team is notified about missing objective device data transmissions (96 occurrences to date during the study); lack of data transmission was quickly resolved as demonstrated by the high overall daily transmission rate (93%)
- Automatic daily remote monitoring identified 96 events that qualified as a predefined proactive care trigger (Figure 3)
- Following a trigger, mean response time by the study remote management team to act upon the trigger was 1.9 days, with issue addressed by 2.0 days (Figure 4)

Figure 3. Proactive Care Triggers in Permanent Implants (96 Events)^a

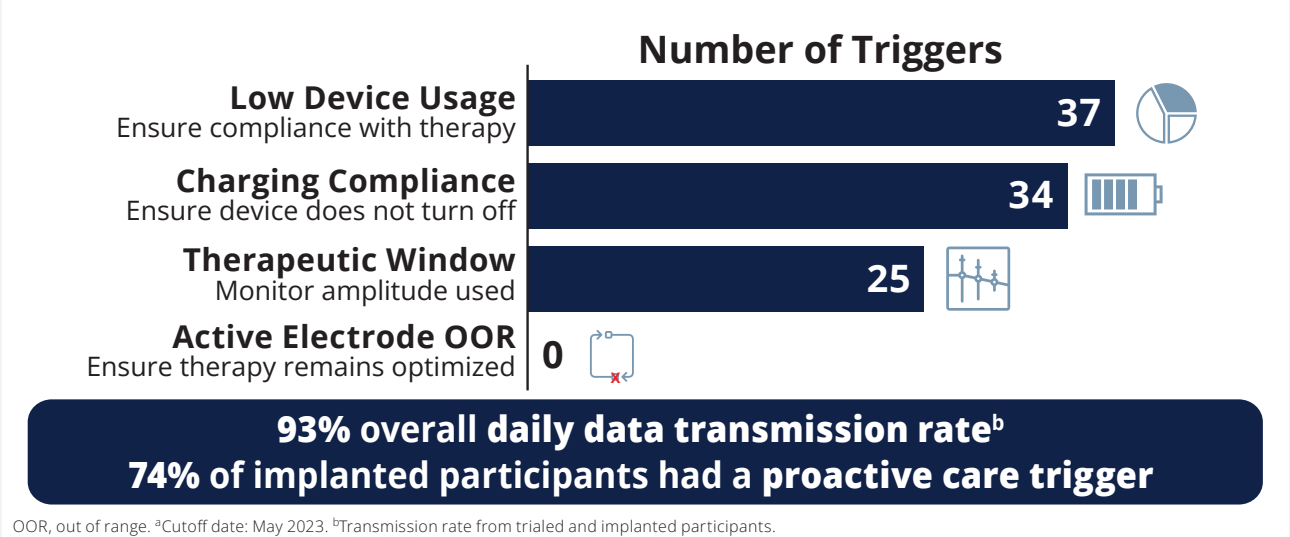
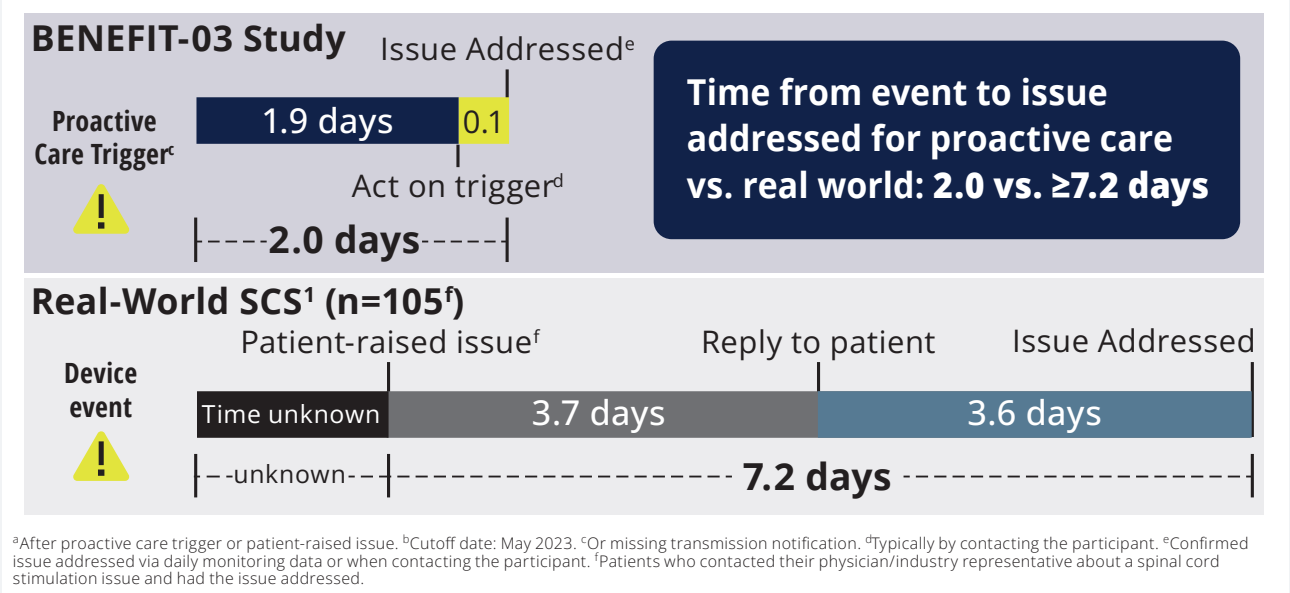


Figure 4. Mean Days to Follow-up^a to Address SCS Issue in BENEFIT-03^b vs. Real-World SCS¹

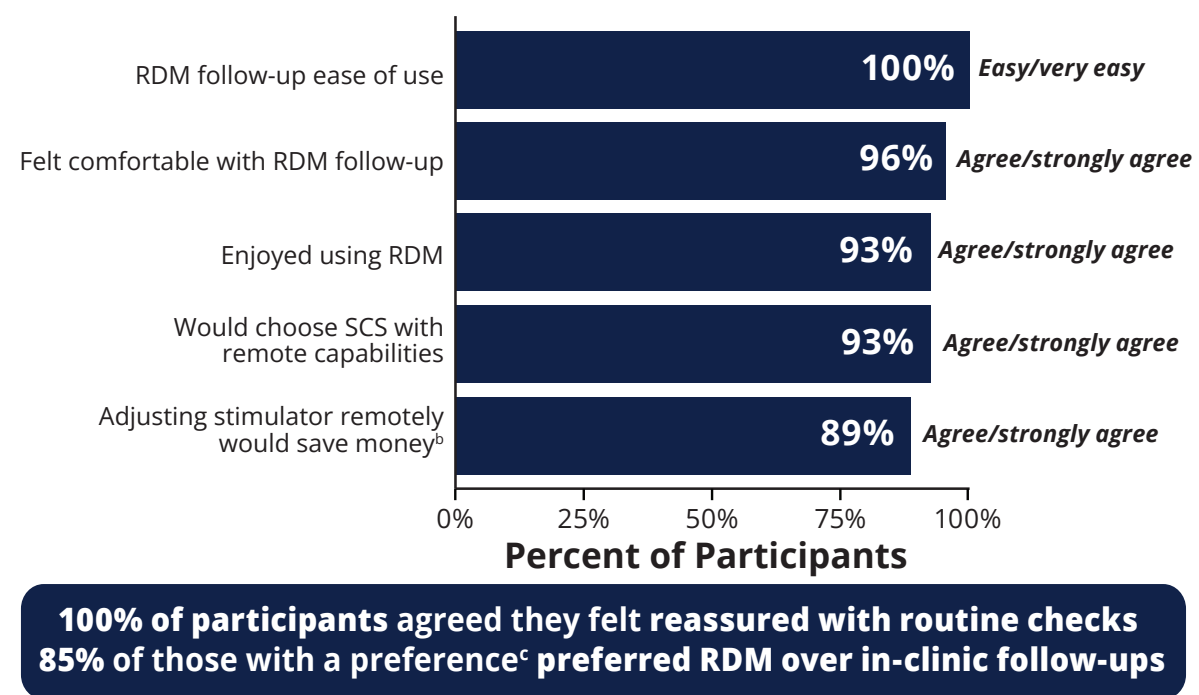


- Remote programming was successfully used to optimize participant's SCS therapy, with most sessions occurring post-implant; this was in part due to trial responders staying with the first program an average of 88% of the trial duration
- This first-in-human implementation of automatic daily remote device monitoring and programming with proactive care establishes a new opportunity to promote optimization of SCS therapy to improve patient care

Participant and Physician Questionnaires

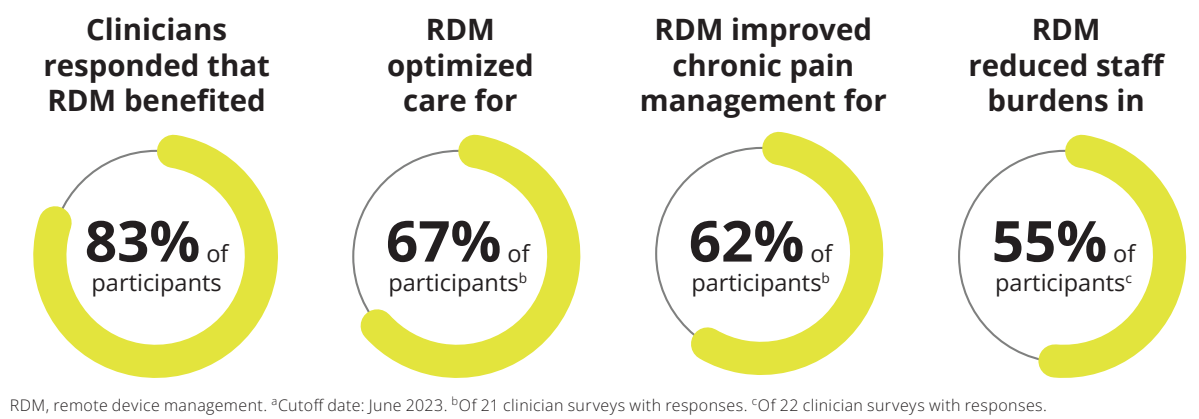
- Implanted participants (n=28 with 6-month data) had positive experiences with remote device management and preferred to check or adjust their device remotely vs. in-clinic (Figure 5)

Figure 5. Implanted Participant Questionnaire (6-Month: n=28)^a



- Clinician surveys for participants with data available indicated remote device management was beneficial to the participant and decreased staff burden (Figure 6)

Figure 6. Clinician Experience Questionnaire for Each Study Participant (6-Month: n=23)^a



Proactive Care: BIOTRONIK Neuro's remote support team may reach out to patients to ensure proper usage of the spinal cord stimulator based on remotely monitored data. BIOTRONIK Neuro does not provide health advice or clinical actions outside the scope of spinal cord stimulator proper usage. This product support is not a replacement for the patient's responsibility to communicate any medical questions or concerns with the physician's office.

^aApproved in the US only; not commercially available outside the US.

[†]At the time of this interim analysis not all participants had completed 3- and 6-month follow-ups. Outcomes may change as additional participant data are collected.

AUTHOR DISCLOSURES

M. Russo has historical minor equity holding in SPR Therapeutics and options in Saluda Medical and Presidio Medical. J. Yu has consulted for Abbott, Nevro, Medtronic, Boston Scientific and participated in research for Nevro, Boston Scientific, Medtronic, Saluda, Biotronik, and Nalu. V. Mohabbati has consulted for Medtronic, Abbott, Saluda, Nevro, and participated in research for Nevro, Medtronic, Abbott, Nalu, and Saluda. K. Amirdelfan has consulted for Medtronic, Boston Scientific, Nevro, Biotronik, and Nalu (minor options). L. Kapural has consulted for Nevro, Abbott, Medtronic, Nalu, Saluda, and Biotronik and participated in research for Nevro, Medtronic, Gimner Medical, Neuros, Saluda, Biotronik, and SPR Therapeutics. P. Verrills has consulted for Presidio, Biotronik, Saluda, and Nalu and has participated in research with Biotronik and Presidio.

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