



78% (7/9) industry-funded studies reported favorable outcomes. The remaining 22% (2/9) showed positive effect of SCS on pain intensity regardless of the stimulation mode. Non-industry funded studies without COI reported unfavorable outcome in 100% (2/2) of cases.

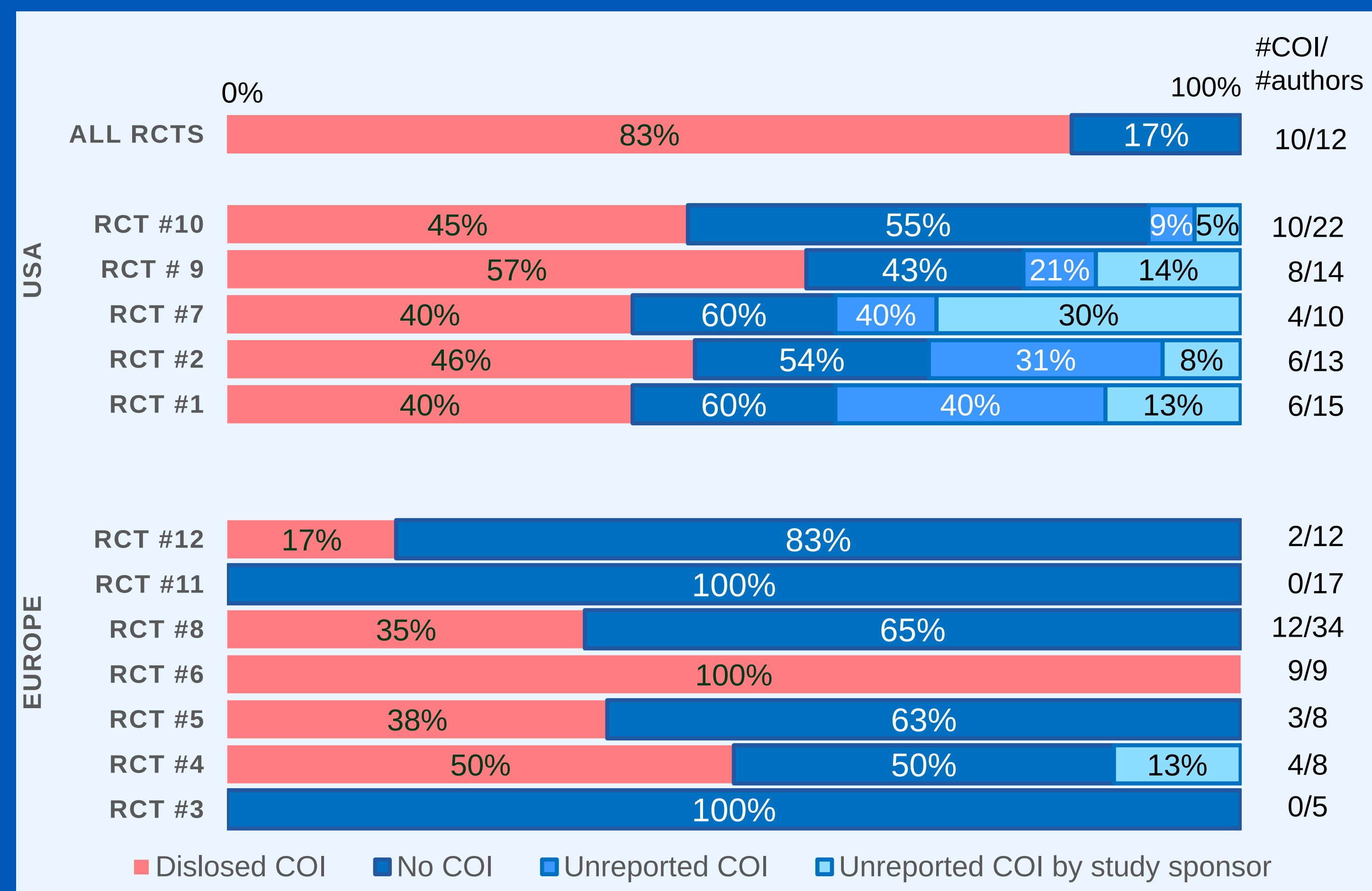


Figure 1. COI of included RCTs. The number (%) of COI is reported for each study. Authors without disclosed COI (No COI) and those with payments listed in the OpenPayments database were identified (Unreported COI) including the source of the payment (Unreported COI by study sponsor).

CONCLUSION

- The majority (75%) of RCTs investigating SCS for chronic pain receive industry funding, potentially introducing significant bias.
- Further industry independent RCTs are needed to verify SCS efficacy in treatment of chronic back and leg pain.

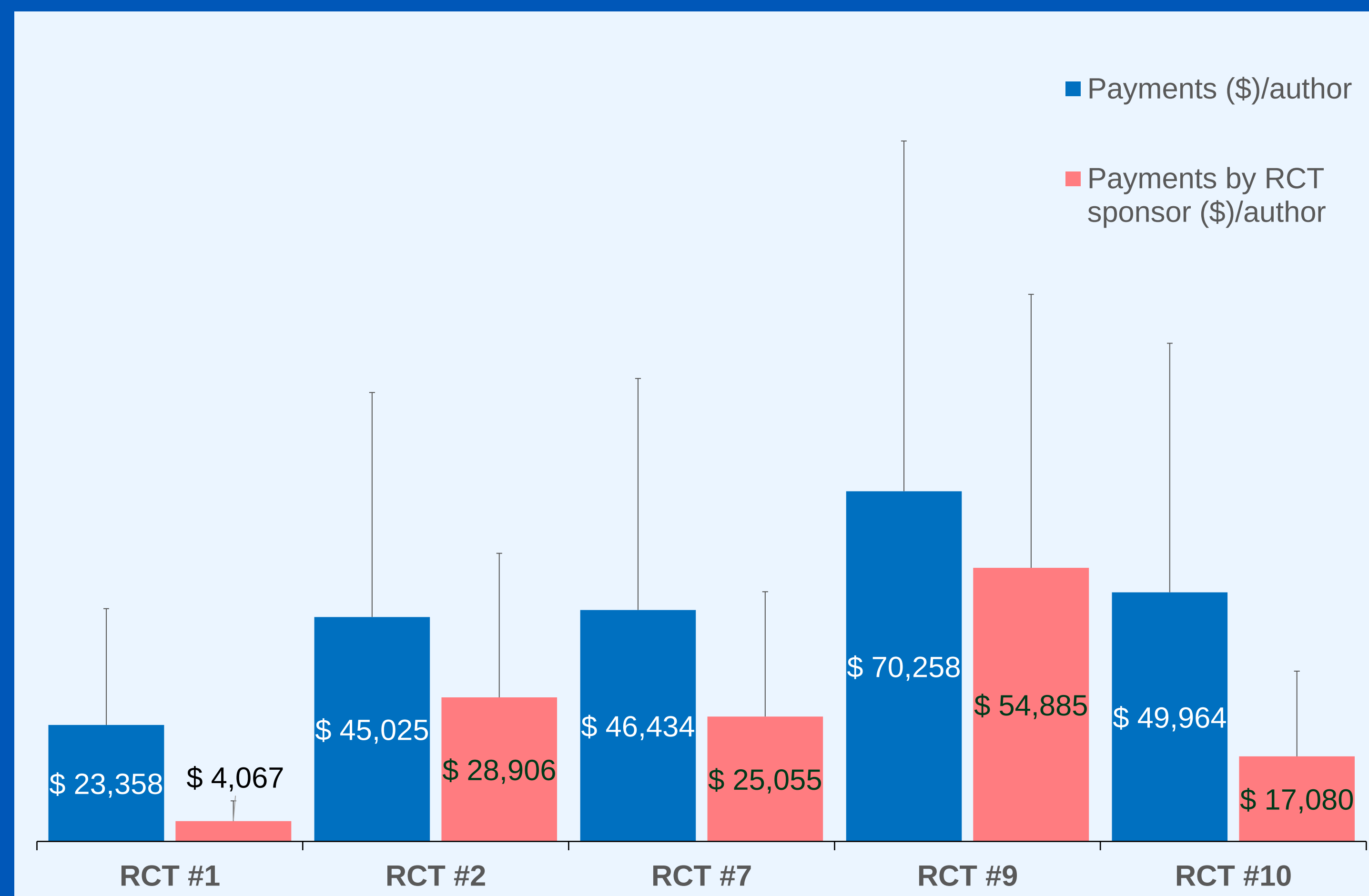


Figure 2. The average payments made to study authors by SCS manufacturers over the period of 3 years. Values presented in U.S. Dollars.

REFERENCES

- Ahn, Rosa, et al., *bmj* 356 (2017).
- Katz, Dana, et al, *The American Journal of Bioethics* 10.10 (2010): 11-17.

A Cross-sectional Analysis of Conflicts of Interest in Randomized Clinical Trials Related to Spinal Cord Stimulation

Johana Klasova, Ryan S. D’Souza

Department of Anesthesiology and Perioperative Medicine, Mayo Clinic, Rochester, MN, USA

INTRODUCTION

- Spinal Cord Stimulation (SCS) efficacy is supported by overwhelmingly positive results in published literature, including randomized controlled trials (RCTs).
- Notable financial contributions from SCS manufacturers can make interventional pain physicians susceptible to conflict of interest (COI) which raise concerns about introducing bias into study design and results presentation^{1,2}.
- We aim to address a research gap on COI in the context of SCS for chronic back pain by investigating the prevalence of COI among SCS-related RCTs and its association with trial outcomes.

METHODS

- Relevant RCTs published after OpenPayments release (2013) were identified.
- Inclusion criteria: RCTs investigating effect of SCS in patients with chronic back and leg pain.
- The extracted data included disclosed COI and payments from SCS manufacturers for each author. Payments in the Research, Education, Food and Beverages, Travel and Lodging categories were not considered COI.

RESULTS

RCT ID	Author	Year	Country	Trial ID	Funding	Desing	Blinding	Primary Outcome
1	Kapural	2015	USA	NCT01609972	Nevro Corp.	Parallel	Open label	10kHz HF-SCS reached non-inferiority and superiority.
2	Kapural	2016	USA	NCT01609972	Nevro Corp.	Parallel	Open label	Long term non-inferiority and superiority was sustained.
3	De Andres	2017	Spain	Not reported	No funding	Parallel	Blinded	No significant difference between HF-SCS and LF-SCS. Superiority wasn't achieved.
4	Al-Kaisy	2018	UK	NCT01750229	Medtronic Inc.	Crossover	Blinded	Frequencies below 5882 Hz provided the same analgesic effect as sham stimulation. 5882Hz stimulation can produce significant back pain relief.
5	Thomson	2018	UK	NTC02549183	Boston Scientific	Crossover	Blinded	Stimulation by 1-10kHz provided equivalent back pain relief (p=0.00002), 1kHz required less charge.
6	Rigoard	2019	France	NTC01697358	Medtronic Inc.	Parallel	Open label	Addition of SCS to OMM provided statistically significant improvements in pain relief.
7	Bolash	2019	USA	Not reported	StimWave Inc.	Parallel	Open label	Non-inferiority of HF-SCS was reached.
8	Rigoard	2021	France	NCT01628237	Grant	Parallel	Blinded	No significant difference between treatments. No further improvement after cross-over.
9	Fishman	2021	USA	NTC03606187	Stimgenics, LLC	Parallel	Open label	The DTM SCS reached non-inferiority.
10	Kapural	2022	USA	NTC03680846	Nevro Corp.	Parallel	Open label	80.9% of 10kHz HF-SCS group were responders in comparison to 1.3% in CMM group.
11	Hara	2022	Norway	NTC03546738	Grant	Crossover	Blinded	No statistically significant effect difference in ODI between B-SCS and placebo.
12	Rigoard	2023	France	NTC03014583	Boston Scientific	Crossover	Blinded	No statistically significant difference in VAS between HF/ B-SCS and LF-SCS.

Table 1. Characteristics and Findings of Included RCTs. HF-SCS: High frequency Spinal Cord Stimulation, LF-SCS: Low Frequency Spinal Cord Stimulation, OMM: Optimal Medical Management, CMM: Conventional Medical Management, DTM SCS: Differential Target Multiplexed SCS, B-SCS: Burst SCS

