**Supplementary Digital Content Table 3. Summary of Adverse Events by System Organ Class**

|  | | ***PTNS (N=111)*** | | ***Sham (N=55)*** | | ***Total (N=166)*** | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| ***System Organ Class*** | ***Preferred Term*** | ***No. of Events*** | ***No. of Subjects (%)*** | ***No. of Events*** | ***No. of Subjects (%)*** | ***No. of Events*** | ***No. of Subjects (%)*** |
| Any | Any | 201 | 73 (66) | 56 | 31 (56) | 257 | 104 (63) |
| Infections and infestations | Any | 39 | 32 (29) | 16 | 13 (24) | 55 | 45 (27) |
|  | Urinary tract infection | 14 | 14 (13) | 4 | 4 (7) | 18 | 18 (11) |
|  | Nasopharyngitis | 8 | 7 (6) | 2 | 2 (4) | 10 | 9 (5) |
|  | Bronchitis | 4 | 4 (4) | 1 | 1 (2) | 5 | 5 (3) |
|  | Sinusitis | 3 | 3 (3) | 1 | 1 (2) | 4 | 4 (2) |
|  | Upper respiratory tract infection | 1 | 1 (1) | 2 | 2 (4) | 3 | 3 (2) |
|  | Eye infection | 2 | 2 (2) | 0 | 0 (0) | 2 | 2 (1) |
|  | Gastrointestinal viral infection | 1 | 1 (1) | 1 | 1 (2) | 2 | 2 (1) |
|  | Tooth infection | 1 | 1 (1) | 1 | 1 (2) | 2 | 2 (1) |
|  | Fungal infection | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Herpes zoster | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Hordeolum | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Influenza | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Localized infection | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Oral candidiasis | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Pharyngitis | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Pneumonia | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Streptococcal infection | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
| Nervous system disorders | Any | 28 | 21 (19) | 8 | 7 (13) | 36 | 28 (17) |
|  | Paresthesia | 16 | 11 (10) | 2 | 2 (4) | 18 | 13 (8) |
|  | Headache | 4 | 4 (4) | 1 | 1 (2) | 5 | 5 (3) |
|  | Sciatica | 2 | 2 (2) | 1 | 1 (2) | 3 | 3 (2) |
|  | Dizziness | 2 | 2 (2) | 0 | 0 (0) | 2 | 2 (1) |
|  | Hypoesthesia | 0 | 0 (0) | 2 | 2 (4) | 2 | 2 (1) |
|  | Amnesia | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Cervical radiculopathy | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Migraine | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Nerve compression | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Somnolence | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Tremor | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
| Gastrointestinal disorders | Any | 30 | 20 (18) | 8 | 7 (13) | 38 | 27 (16) |
|  | Diarrhea | 9 | 6 (5) | 1 | 1 (2) | 10 | 7 (4) |
|  | Constipation | 6 | 4 (4) | 2 | 2 (4) | 8 | 6 (4) |
|  | Abdominal pain upper | 1 | 1 (1) | 2 | 2 (4) | 3 | 3 (2) |
|  | Abdominal pain | 2 | 2 (2) | 0 | 0 (0) | 2 | 2 (1) |
|  | Hiatus hernia | 2 | 2 (2) | 0 | 0 (0) | 2 | 2 (1) |
|  | Nausea | 2 | 2 (2) | 0 | 0 (0) | 2 | 2 (1) |
|  | Rectal hemorrhage | 2 | 2 (2) | 0 | 0 (0) | 2 | 2 (1) |
|  | Abdominal discomfort | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Anal paresthesia | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Chapped lips | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Colitis | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Flatulence | 2 | 1 (1) | 0 | 0 (0) | 2 | 1 (1) |
|  | Gastritis | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Hematochezia | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Vomiting | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
| Musculoskeletal and connective tissue disorders | Any | 25 | 18 (16) | 5 | 5 (9) | 30 | 23 (14) |
|  | Arthralgia | 5 | 3 (3) | 2 | 2 (4) | 7 | 5 (3) |
|  | Pain in extremity | 7 | 5 (5) | 0 | 0 (0) | 7 | 5 (3) |
|  | Back pain | 3 | 3 (3) | 1 | 1 (2) | 4 | 4 (2) |
|  | Muscle spasms | 3 | 3 (3) | 0 | 0 (0) | 3 | 3 (2) |
|  | Diastasis recti abdominis | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Joint swelling | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Limb discomfort | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Muscle tightness | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Muscle twitching | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Musculoskeletal pain | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Myalgia | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Neck pain | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Osteoarthritis | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
| General disorders and administration site conditions | Any | 28 | 18 (16) | 1 | 1 (2) | 29 | 19 (11) |
|  | Medical device site hemorrhage | 14 | 9 (8) | 0 | 0 (0) | 14 | 9 (5) |
|  | Application site pain | 2 | 2 (2) | 0 | 0 (0) | 2 | 2 (1) |
|  | Chest pain | 1 | 1 (1) | 1 | 1 (2) | 2 | 2 (1) |
|  | Injection site pain | 2 | 2 (2) | 0 | 0 (0) | 2 | 2 (1) |
|  | Adverse drug reaction | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Application site paresthesia | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Asthenia | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Chills | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Death | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Influenza like illness | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Malaise | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Medical device site pain | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Puncture site pain | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
| Injury, poisoning and procedural complications | Any | 14 | 11 (10) | 2 | 2 (4) | 16 | 13 (8) |
|  | Fall | 7 | 6 (5) | 1 | 1 (2) | 8 | 7 (4) |
|  | Contusion | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Femur fracture | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Joint injury | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Ligament sprain | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Limb injury | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Post procedural hemorrhage | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Procedural hemorrhage | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Procedural pain | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
| Respiratory, thoracic and mediastinal disorders | Any | 10 | 9 (8) | 1 | 1 (2) | 11 | 10 (6) |
|  | Cough | 2 | 2 (2) | 1 | 1 (2) | 3 | 3 (2) |
|  | Dry throat | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Dyspnea | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Nasal congestion | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Pneumothorax | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Pulmonary hypertension | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Sinus disorder | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Throat irritation | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Upper-airway cough syndrome | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
| Renal and urinary disorders | Any | 2 | 2 (2) | 6 | 5 (9) | 8 | 7 (4) |
|  | Dysuria | 1 | 1 (1) | 1 | 1 (2) | 2 | 2 (1) |
|  | Pollakiuria | 0 | 0 (0) | 2 | 2 (4) | 2 | 2 (1) |
|  | Urge incontinence | 0 | 0 (0) | 2 | 2 (4) | 2 | 2 (1) |
|  | Urinary incontinence | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Urinary retention | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
| Skin and subcutaneous tissue disorders | Any | 8 | 7 (6) | 0 | 0 (0) | 8 | 7 (4) |
|  | Alopecia | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Blister | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Eczema | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Ingrowing nail | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Rash | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Rash generalized | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Skin discoloration | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Skin reaction | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
| Investigations | Any | 4 | 3 (3) | 1 | 1 (2) | 5 | 4 (2) |
|  | Blood potassium decreased | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Blood pressure increased | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Colonoscopy | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Endoscopy gastrointestinal | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Esophagogastroduodenoscopy | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
| Reproductive system and breast disorders | Any | 4 | 3 (3) | 2 | 1 (2) | 6 | 4 (2) |
|  | Fibrocystic breast disease | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Pelvic pain | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Uterine hemorrhage | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Vaginal discharge | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Vulvovaginal pain | 2 | 1 (1) | 0 | 0 (0) | 2 | 1 (1) |
| Cardiac disorders | Any | 1 | 1 (1) | 2 | 2 (4) | 3 | 3 (2) |
|  | Atrial fibrillation | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Myocardial infarction | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Tachycardia | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
| Surgical and medical procedures | Any | 1 | 1 (1) | 2 | 2 (4) | 3 | 3 (2) |
|  | Abdominal hernia repair | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Abdominoplasty | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Medical device removal | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
| Eye disorders | Any | 2 | 2 (2) | 0 | 0 (0) | 2 | 2 (1) |
|  | Chalazion | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Photopsia | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
| Immune system disorders | Any | 1 | 1 (1) | 1 | 1 (2) | 2 | 2 (1) |
|  | Drug hypersensitivity | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Multiple allergies | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
| Metabolism and nutrition disorders | Any | 2 | 2 (2) | 0 | 0 (0) | 2 | 2 (1) |
|  | Gluten sensitivity | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Gout | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
| Vascular disorders | Any | 2 | 2 (2) | 0 | 0 (0) | 2 | 2 (1) |
|  | Hot flush | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
|  | Hypertension | 1 | 1 (1) | 0 | 0 (0) | 1 | 1 (1) |
| Hepatobiliary disorders | Any | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |
|  | Hepatic steatosis | 0 | 0 (0) | 1 | 1 (2) | 1 | 1 (1) |

Abbreviations:

PTNS, Percutaneous tibial nerve stimulation.