Cleveland Clinic
Innovations

PRODUCT
A machine learning algorithm, used to predict patient outcomes following the overactive bladder treatment Onabotulinumtoxin A (OBTX-A) injection and sacral neuromodulation (SNM).
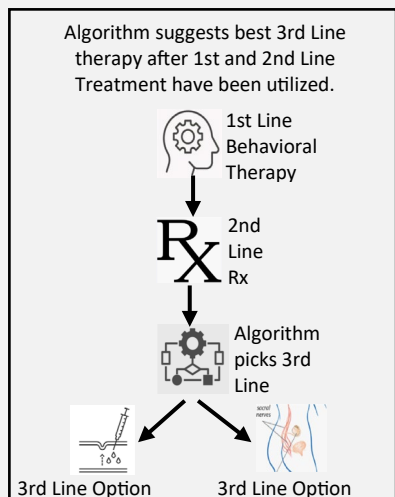
INDICATIONS
Accurate prediction of response to onabotulinumtoxin-A treatment or sacral neuromodulation in overactive bladder.

VALUE PROPOSITION
- Novel approach to predict any outcome based on heterogeneous data within or outside the urologic or medical field
- Quickly predict the treatment option with the best success rate

DEVELOPMENT STAGE
Proof of concept established.

Algorithm suggests best 3rd Line therapy after 1st and 2nd Line Treatment have been utilized.

1st Line Behavioral Therapy

2nd Line Rx

Algorithm picks 3rd Line

3rd Line Option   3rd Line Option

CONTACT INFORMATION
Jerry Wilmink, Ph.D.,MBA
Director, BD & Licensing
Innovations
wilminj@ccf.org, (216) 314-6397
Case IDF 2022-051

Algorithms for Prediction of Overactive Bladder Response to Third Line Treatment Options

Glenn Werneburg MD PhD, Sandip Vasavada MD, Howard B. Goldman MD
Cleveland Clinic

UNMET NEED
Electronic medical records accumulate a wealth of complex data, which can become unmanageable for providers to assimilate and to make optimal clinical treatment decisions without assistance. Currently, there are no streamlined methods established to guide clinical decision-making between Onabotulinumtoxin A (OBTX-A) and sacral neuromodulation (SNM) treatment, or to predict rates of post-procedural urinary tract infection, for patients with overactive bladder refractory to medication. There is an unmet need for an algorithm that can assimilate diverse clinical data, including urodynamic and non-urodynamics variable sets, to accurately predict treatment outcomes. An algorithm used to assist physicians in selecting an optimal treatment plan tailored to the individual patient.

SOLUTION
Inventors at Cleveland Clinic have established the development and training of algorithms through the novel application of reproducing Kernel Krein Space (RKKS) and "operator splitting" techniques, to predict treatment response and post-procedural urinary tract infection. It allows for the accurate prediction of objective response, subjective improvement in symptoms, and urinary tract infection following OBTX-A or SNM treatment for overactive bladder. The algorithms were superior to human experts and other algorithms in outcome prediction for OBTX-A and SNM.

PUBLICATIONS
Werneburg, G. T., *et al*. Neural networks outperform expert humans in predicting patient impressions of symptomatic improvement following overactive bladder treatment. Int. Urogynecology J., 34(5), 1009-1016 (2023).

Werneburg, G.T., *et al*. Machine learning provides an accurate prognostication model for refractory overactive bladder treatment response and is noninferior to human experts. Neurourology and urodynamics vol. 41,3 (2022).

Werneburg, G.T., *et al*. External validation demonstrates machine learning models outperform human experts in prediction of objective and patient-reported overactive bladder treatment outcomes. Under Review.