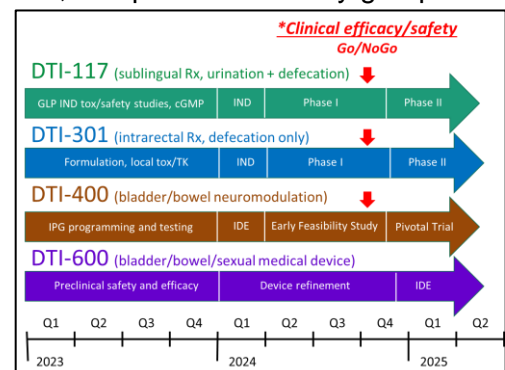
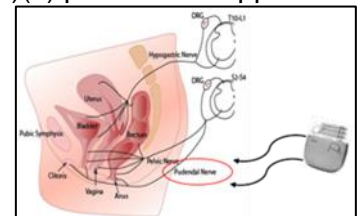
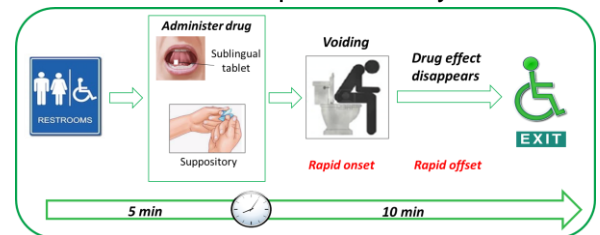
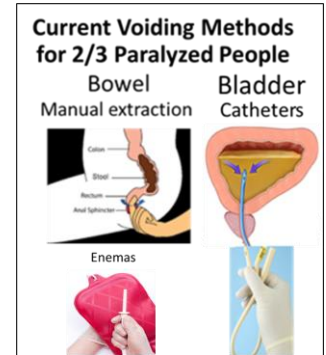


DIGNIFY THERAPEUTICS, LLC

- **Mission statement:** Dignify Therapeutics develops novel drug and medical device therapies to restore voluntary control of bladder/bowel function and eliminate manual bowel programs, bladder catheters, and adult diapers.
- **Severe, unmet medical need:** Bladder and bowel dysfunction are terrible problems for people with neurologic injury or disease (2 MM) and diabetic neuropathy (4 MM). Inability to control voiding is the number 1 reason for institutionalization of the elderly (1 MM). NIH, Veterans Administration Medical Centers, and patient advocacy groups strongly support our programs. Fast-Track FDA designations are expected. No FDA-approved competition exists for any Dignify program (i.e. all are “first-in-indication” therapies).
- **Reimbursement, pricing, and market opportunity:** 3rd party analysis of defecation drug products indicates Tier 2 placement, \$7,000-8,000/year price point, and ~ \$1B/year peak US sales for each with COGS < 10% of sale price. Device program estimates \$500-\$800K/year.
- **Highly de-risked, rapid, inexpensive clinical development:** Clinical evidence supports all therapies, and translational animal models in SCI, diabetes, and aging are highly predictive of clinical responses. Clinical proof-of-concept (POC) is immediately established in Phase 1 trials for drugs and Early Feasibility Studies for the devices, which occurs within 2 years of funding for 3 of 4 programs. Clinical protocols are written; and investigators, sites, and CROs are engaged for patient studies, which occurs within 3 years of funding. FDA-approved partners engaged to provide drug substances, drug products, and devices for clinical development. Simple phase 3 trials for drugs and pivotal trials for devices use inexpensive diary and QoL.
- **IP:** Issued patents for 3 programs, application in progress for DTI-600, additional formulation patents expected.
- **On-demand, rapid-onset, short-duration, drug-induced voiding therapy:** There are no safe, efficacious, and convenient drug therapies available for inducing micturition or defecation. Current therapy include bladder catheterization, manual bowel programs, enemas, laxatives, and diapers. Two distinct drug programs (DTI-117 – sublingual, DTI-301 - suppository) are ready for IND-enabling studies with positive pre-IND meeting with FDA for one, while the other provides a 505(b)(2) path to IND approval.
- **Medical devices:** Positive feedback was obtained at our Q-sub meeting from the FDA for DTI-400, which will be the first FDA approved neuromodulation device for neurogenic bladder/bowel dysfunction, and publications indicate it is superior to Medtronic sacral neuromodulation for non-neurogenic dysfunctions. DTI-600 preclinical efficacy studies are funded by the NIH.
- **Financial support:** \$3.4 M seed (Founders, RA Capital, Eshelman Ventures); \$15 M non-dilutive grants (NIH).
- **Community support:** NIH, Veterans Administration Medical Centers, and patient advocacy groups.
- **Use of \$30 M “A Round” Proceeds:** DTI-117, DTI-301, and DTI-400 through clinical POC in patients. IDE submission for DTI-600.
- **Team:** [Edward Burgard, PhD](#), Pres
[Karl B. Thor, PhD](#), CSO
[Anthony Ditonno](#), Exec Chair
[Nadia Rupniak, PhD](#); EVP Drug Dev
[Dan Ricca, PhD](#), VP Chem
[Lesley Marson, PhD](#), VP Preclin



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