



DEVELOPING **A NEW PARADIGM** IN BOWEL AND BLADDER MANAGEMENT

October 2026



DIGNIFY THERAPEUTICS AT A GLANCE

- First on-demand drugs for dysfunctional bowel and bladder
- Two novel programs: **DTI-117** (NK2R agonist) and **DTI-301** (TRPV1 agonist)
- Issued method-of-use patents covering both programs
- Underserved neurogenic bowel dysfunction (NBD) populations, starting with spinal cord injury (~312K U.S. patients) and expanding to MS (~1.0M) and constipation (30M+)
- \$20M+ in non-dilutive funding to date

DTI-117 NK2R agonist

Phase 1 SAD, NIH-funded

- ◆ **Oct 2026** Phase 1 SAD (intramuscular formulation)
- ◆ **Nov 2026** FPI (first dosing)
- ◆ **Jan 2027** Preliminary topline data
- ◆ **Mid-2027** Initiate sublingual formulation
- ◆ **Mid-2028** Safety + POC data in patients

DTI-301 TRPV1 agonist Suppository

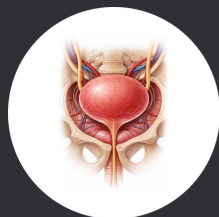
- ◆ **Q1 2028** Topline SAD data (healthy volunteers)
- ◆ **Q1 2029** Topline MAD data (spinal cord injury)

Grant funded IND enabling studies

CURRENT STANDARD OF CARE

Pharmacologic Alternatives

Bladder voiding



Bethanechol



Bowel voiding

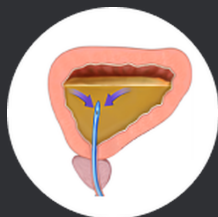


Laxatives

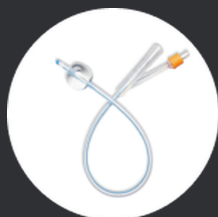


Manual Treatments

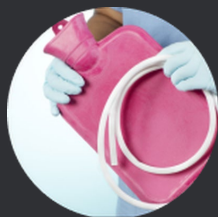
Bladder voiding



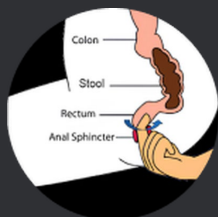
Catheters



Bowel voiding



Enemas



Manual extraction



DTI-117

ENABLING ON-DEMAND, **PATIENT-CONTROLLED EVACUATION
IN NEUROGENIC BOWEL AND BLADDER DYSFUNCTION**

A New Paradigm in Bowel and Bladder Management

LEAD PROGRAM DTI-117 HIGHLIGHTS

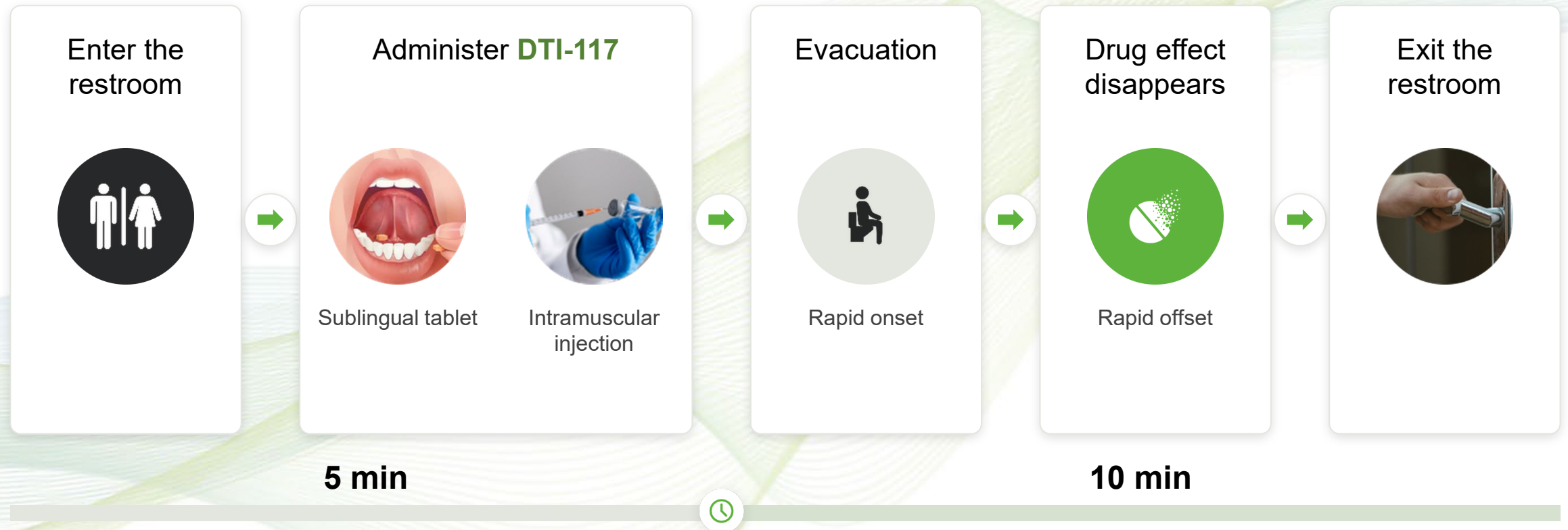
DTI-117 (IM): a new drug therapy that restores controlled evacuation to patients with neurogenic bowel and bladder dysfunction

- Phase 1 single-ascending dose (SAD) study funded by the NIH
- Planned FPS for Phase 1 SAD study: Oct 2026
- Planned FPI for Phase 1 SAD study: Nov 2026
- Preliminary topline data available January 2027

Abbreviations: FPS = first patient screened; FPI = first patient in; IM = intramuscular

First pharmaceutical to enable patient-controlled evacuation and replace invasive bowel and bladder programs

PATIENT-CONTROLLED, ON-DEMAND EVACUATION



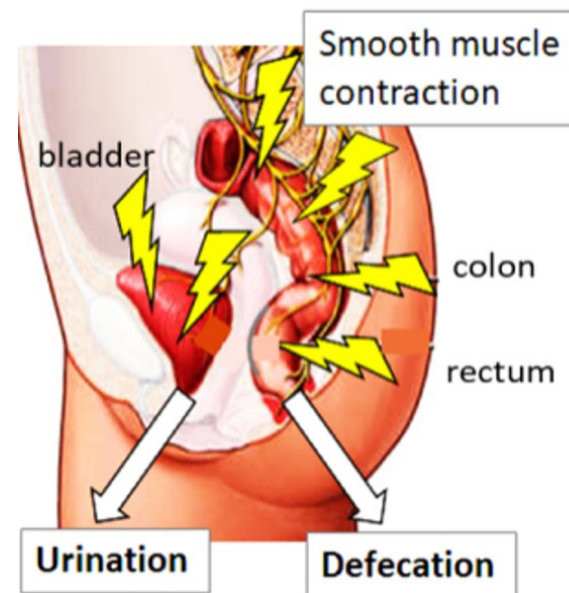
A short-acting trigger for evacuation, not a chronic motility enhancer

DTI-117

Pharmacological Properties

- Neurokinin NK-2 receptor agonist
- Potent (nM) / Selective (1000x)
 - Nonclinical ED₈₀ = 0.03 - 0.1 mg/kg
- Small peptide
 - No hepatic metabolism
- Rapid absorption
 - 2-5 minutes
 - Sublingual, intranasal, intramuscular
- Rapid elimination
 - Plasma t_{1/2} ~ 10 minutes

Selective NK2R activation produces direct colorectal smooth muscle contraction



DTI-117: PRECLINICAL SUMMARY

Efficacy

- Rats, minipig, dogs all respond similarly
- >80% defecation and urination following IM injections of **0.1 mg/kg**
- Urination, defecation occurred ~ 5 min after dosing
- All effects resolved ~ 15 min after dosing

Safety

- Infrequent, mild, transient skin flushing at doses > 0.1 mg/kg
- NOAEL – **2 mg/kg (rats), 3 mg/kg (minipig)**
- All high-dose adverse events are secondary to mechanism of action
 - Abdominal cramping, straining to defecate, diarrhea, emesis
 - High-dose adverse events resolve by 30-45 min
- No cardiovascular, respiratory, or CNS safety concerns

Sources: Thor KB, et al. Preclinical Safety, Efficacy, and PK of DTI-117, an NK2 Receptor Peptide Agonist, in Minipigs: A Proposed “Rapid-onset, Short-duration, On-Demand Defecation” Treatment for Constipation Due to Dysfunctional Defecation. Poster P0808 presented at the American College of Gastroenterology (ACG) 2026 Annual Scientific Meeting, Nashville, TN; October 11, 2026.

DTI-117: PHASE 1 SAD STUDY DESIGN

40 participants • 5 dose cohorts • 0.03–0.3 mg/kg

1 Enroll

Forty participants assigned across the SAD study

2 Start Cohort

Sentinel subjects included for risk-managed dosing

3 Dose Escalate

Five cohorts spanning 0.03–0.3 mg/kg

4 Treat / Control

Each cohort includes active and placebo subjects

5 Review

PK and clinical labs evaluated between cohorts

Dose-escalation rhythm

Evaluate safety, PK, and clinical laboratory data before moving to the next cohort.
Repeat until all five cohorts are complete.

Cohort 1



Cohort 2



Cohort 3



Cohort 4



Cohort 5



DTI-301

ENABLING ON-DEMAND, **PATIENT-CONTROLLED EVACUATION
IN NEUROGENIC BOWEL DYSFUNCTION**

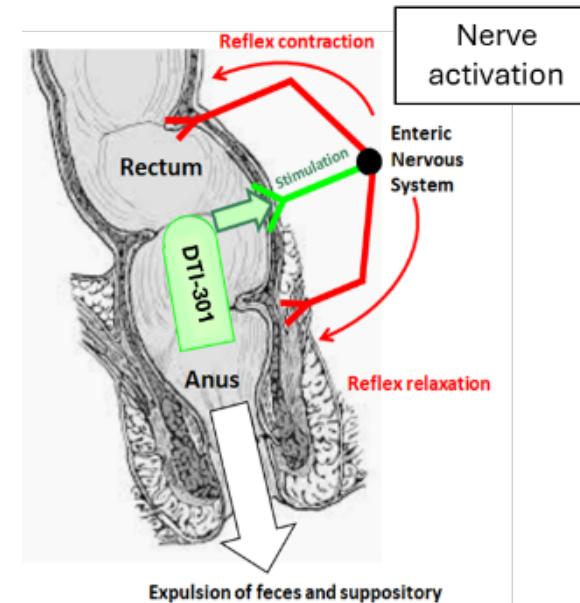
A New Paradigm in Bowel and Bladder Management

DTI-301

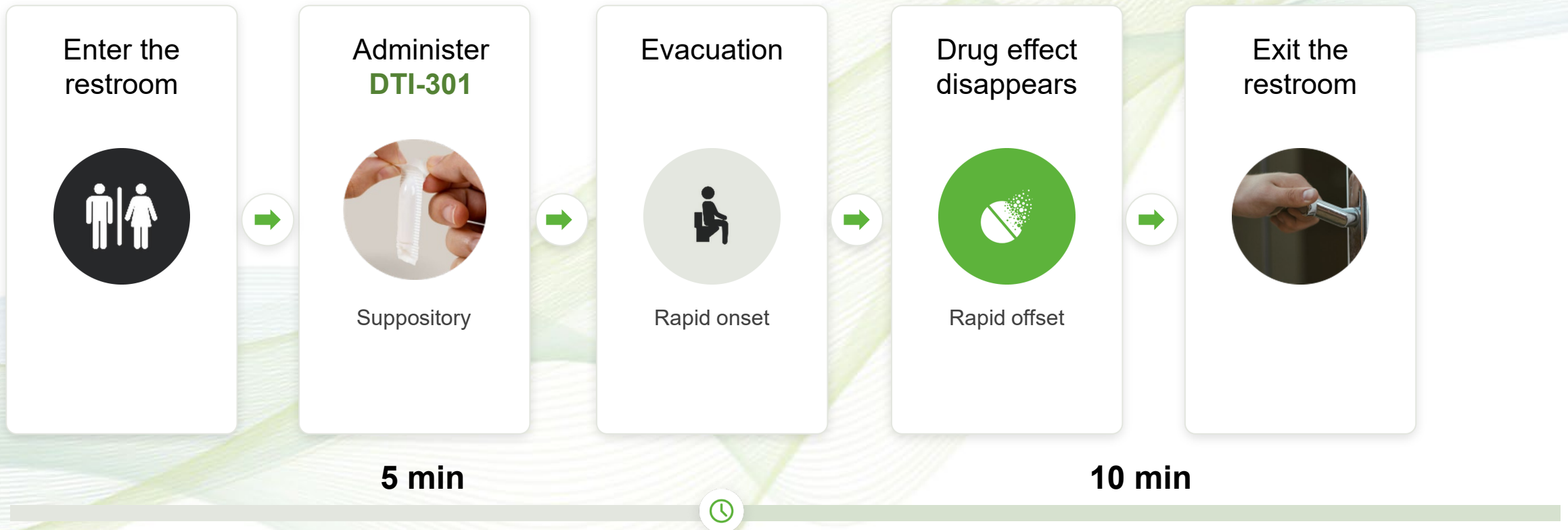
Pharmacological Properties

- **TRPV1 agonist** delivered locally via rectal suppository
- Activates **sensory neural pathways** that trigger the defecation reflex
- Produces **rapid, coordinated colorectal contractions and bowel evacuation**
- Designed for **minimal systemic exposure** and localized pharmacologic activity
- **Short-acting, on-demand effect**, with drug expelled during defecation

Selective TRPV1 activation stimulates rectal sensory pathways, initiating a local neural reflex that promotes coordinated bowel emptying.



PATIENT-CONTROLLED, **ON-DEMAND EVACUATION**



*A **short-acting trigger** for evacuation, not a chronic motility enhancer*

DTI-301: DEVELOPMENT PLAN

Completed Preclinical Animal Studies

- Demonstrated **rapid, dose-dependent colorectal contractions and bowel evacuation**
- Confirmed activity in **spinal cord injury and diabetic animal models**
- Validated the **TRPV1-mediated neurogenic mechanism of action**
- Demonstrated **suppository formulation feasibility and pharmacologic activity**
- Characterized **PK, low systemic exposure, and repeat-dose response**

Regulatory/IND Enabling Studies Grant funded

- Dog Toxicity
- Rat Study

Clinical Development in Australia

- Phase 1 SAD/MAD
- Phase 2a/2b

MARKET OPPORTUNITY: ~900K PATIENTS & >\$6B REVENUES

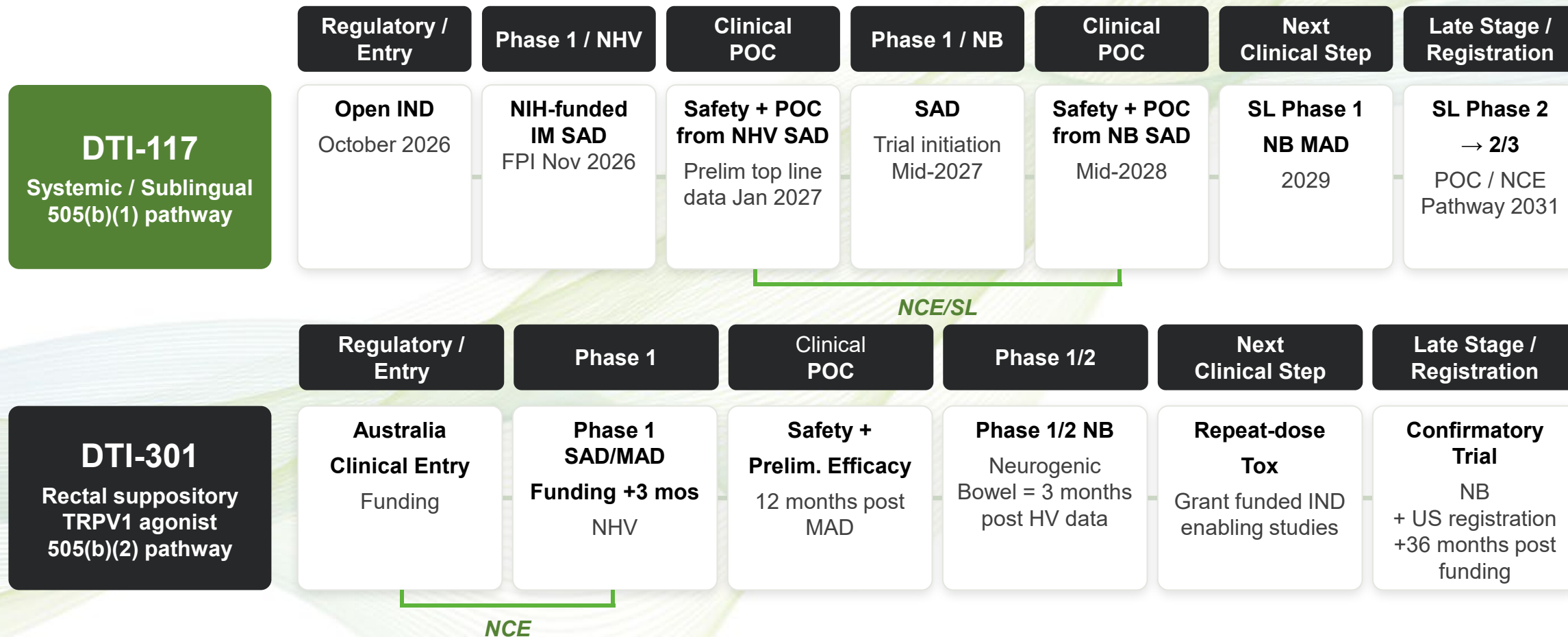
Pricing
assumption **\$6,500**
payor validated

	Patient Prevalence	Market Penetration	Projected Treated Patients	Projected Revenue (USD)
BEACHHEAD SCI-related neurogenic bowel / bladder U.S. SCI prevalence	~312K	~32%	100K	\$650M
EXPANSION MS-related neurogenic bowel / bladder U.S. multiple sclerosis prevalence	~1.0M	~21%	210K	\$1.4B
LONGER-TERM UPSIDE Chronic idiopathic constipation U.S. adult CIC estimate	30M+	~2.1%	630K	\$4.0B

Projected treated patients = patient prevalence × market penetration. Projected revenue = projected treated patients × \$6,500 per patient per year. Pricing assumption based on NIH payor survey. Figures do not reflect net pricing, reimbursement, or launch timing adjustments. Revenue scenarios are illustrative and not probability-adjusted forecasts or company guidance. Prevalence figures are rounded.

Sources: NSCISC 2026 (SCI); National MS Society 2026; AGA/ACG guideline and related epidemiology for chronic idiopathic constipation.

DEVELOPMENT PATHWAY FOR DTI-117 AND DTI-301



Abbreviations: FPI = first patient in; NHV = normal healthy volunteers; IM = intramuscular; NB = neurogenic bowel; SAD = single ascending dose; MAD = multiple ascending dose; POC = proof of concept; NCE = new chemical entity; SL = sublingual.

PLANNED \$75M **SERIES A** FINANCING: USE OF PROCEEDS

- Q1/27 Top line data DTI 117 SAD Healthy Volunteer preliminary topline data announced
- Q2/28 Top line data DTI 117 SAD Neurogenic Bowel pt data announced
- Q1/28 Top line DTI 301 SAD Healthy Volunteer data announced
- Q1/29 Top line DTI 301 MAD Spinal Cord Injury data announced
- Q1/27 Initiate Sublingual Formulation for DTI 117
- In license two novel compounds for both programs to extend product life cycle

~\$25M

- Complete clinical development/regulatory submissions for both programs

~\$50M

NEUROGENIC PATIENT ADVOCACY GROUPS





Dignify
Therapeutics

Restoring **bowel and bladder control** for people with neurological disorders, diabetes, and the elderly

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