



RESTORING **BOWEL AND BLADDER**  
**CONTROL** FOR PEOPLE WITH  
NEUROLOGICAL DISORDERS, DIABETES,  
AND THE ELDERLY



# INVESTMENT HIGHLIGHTS



\$20M in historical non-dilutive funding

Raising Series A

- Safety and proof of concept in NHV
- Safety and proof of concept in patients
- In-license life cycle extension program



Accelerate sublingual development program



Robust IP coverage



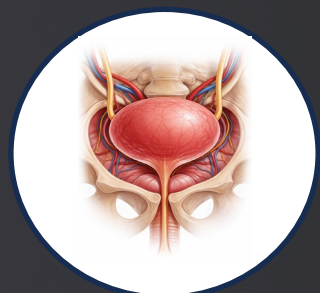
Big underserved, unrecognized markets

**First Rx On-Demand  
Drugs for Dysfunctional  
Bowel and Bladder**

# CURRENT STANDARD OF CARE

## Pharmacologic Alternatives

### Bladder voiding



Bethanechol



### Bowel voiding

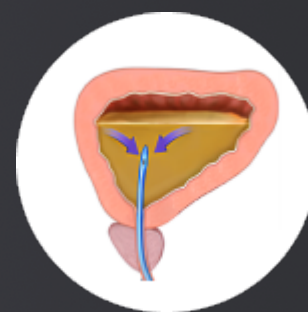


Laxatives

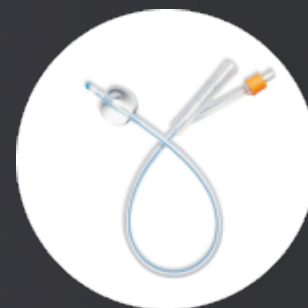


## Manual Treatments

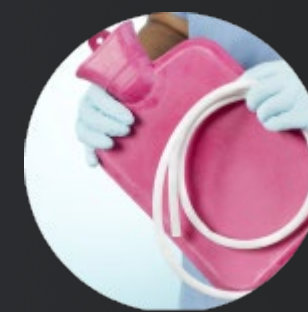
### Bladder voiding



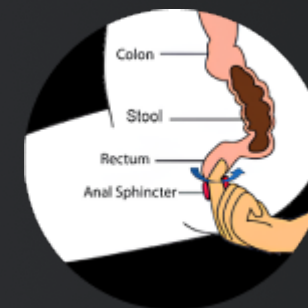
Catheters



### Bowel voiding



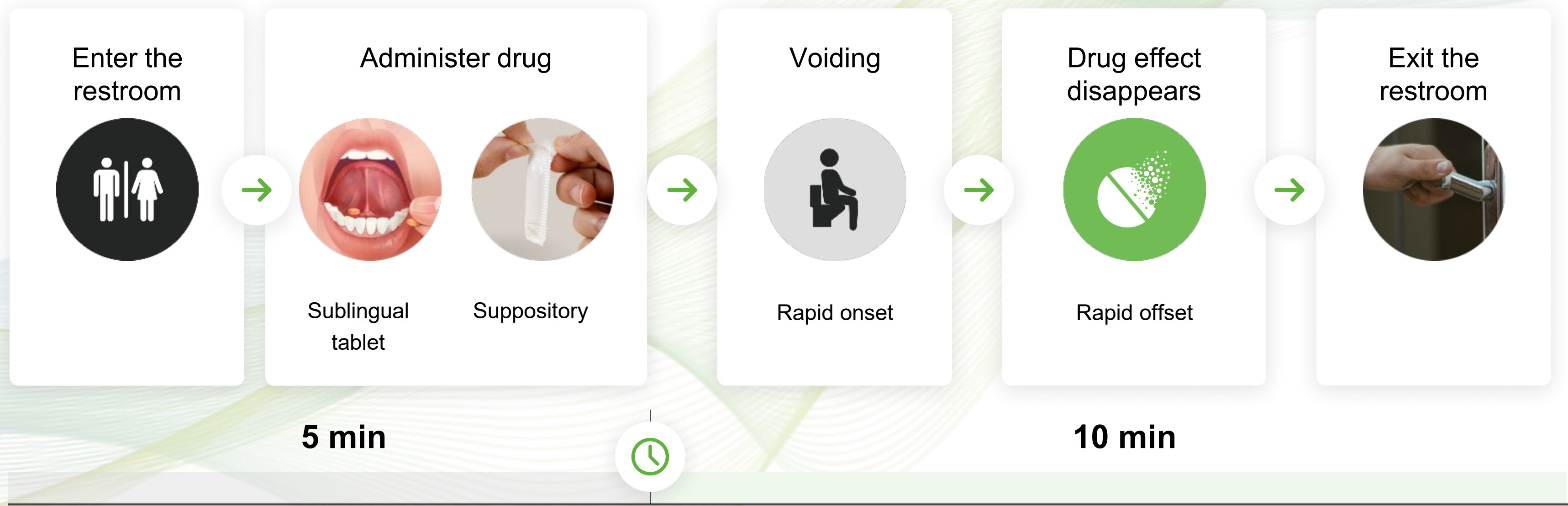
Enemas



Manual extraction

# DIGNIFY'S APPROACH:

## Patient Controlled On-Demand Voiding



# DRUG PROGRAMS

## DTI-117

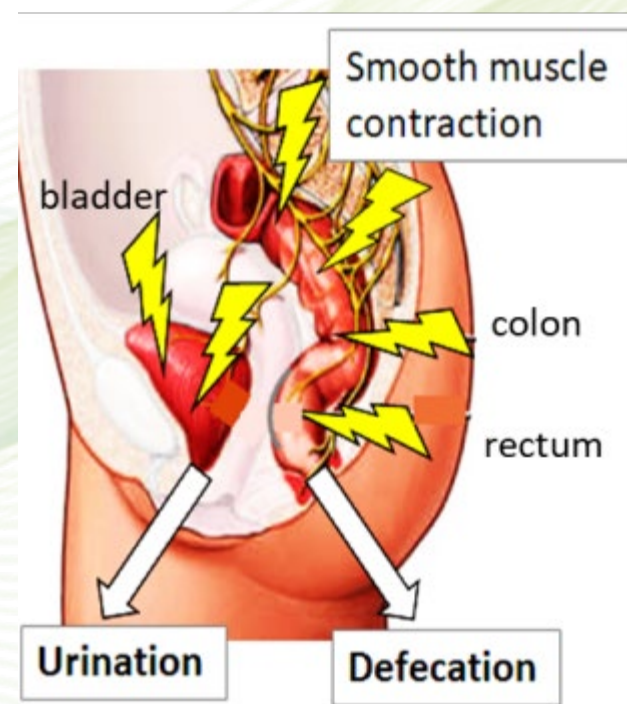
On-demand **urination and defecation**



Sublingual



Intramuscular

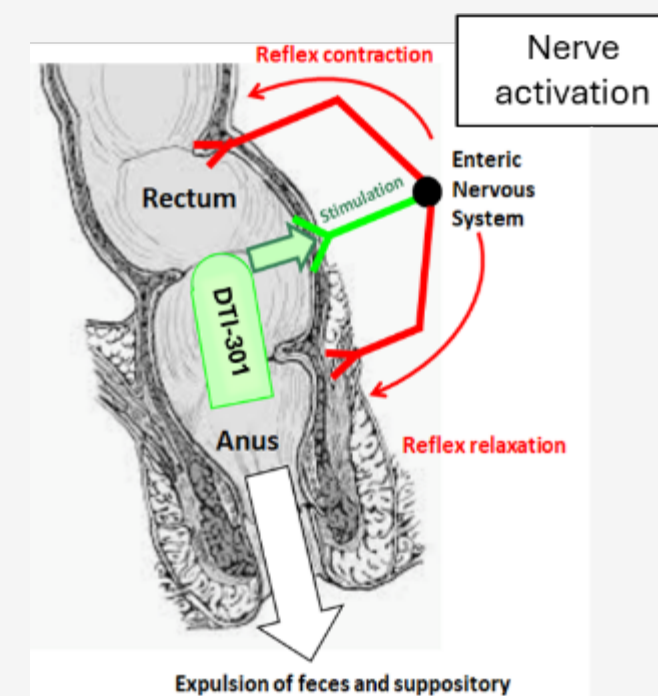


## DTI-301

On-demand **defecation**

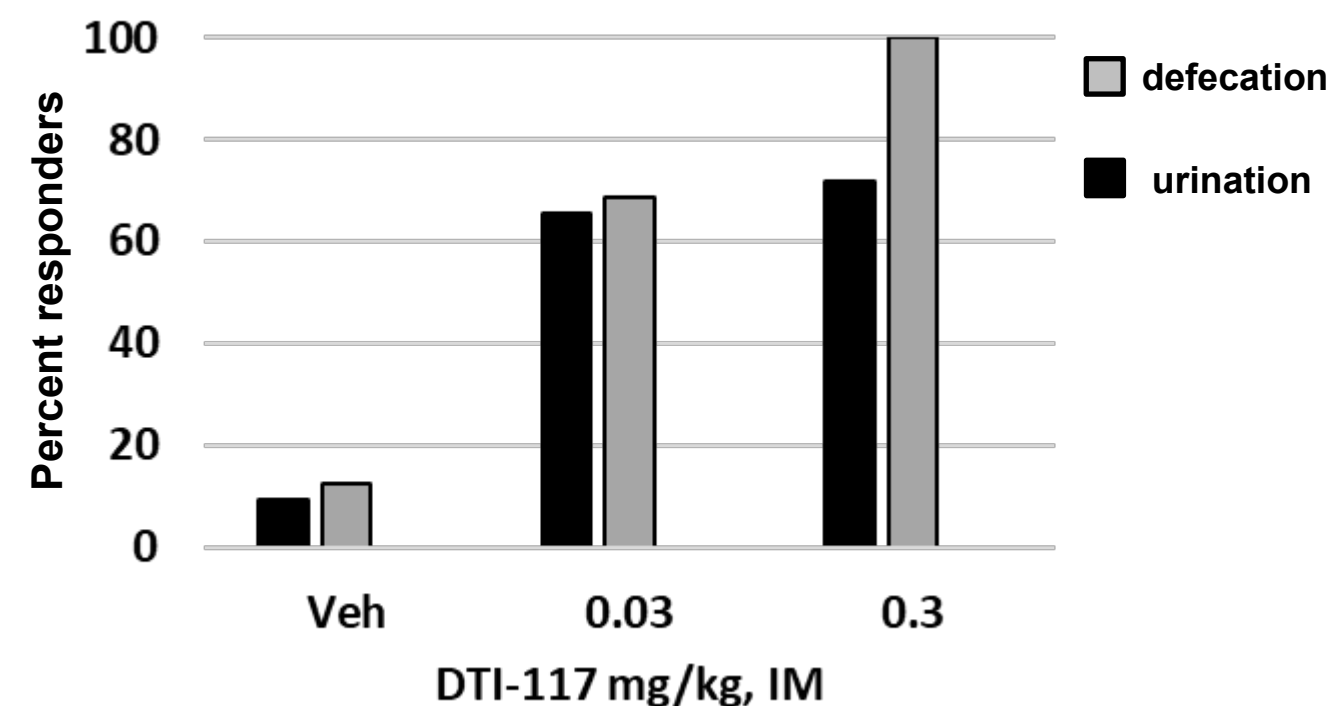


Suppository

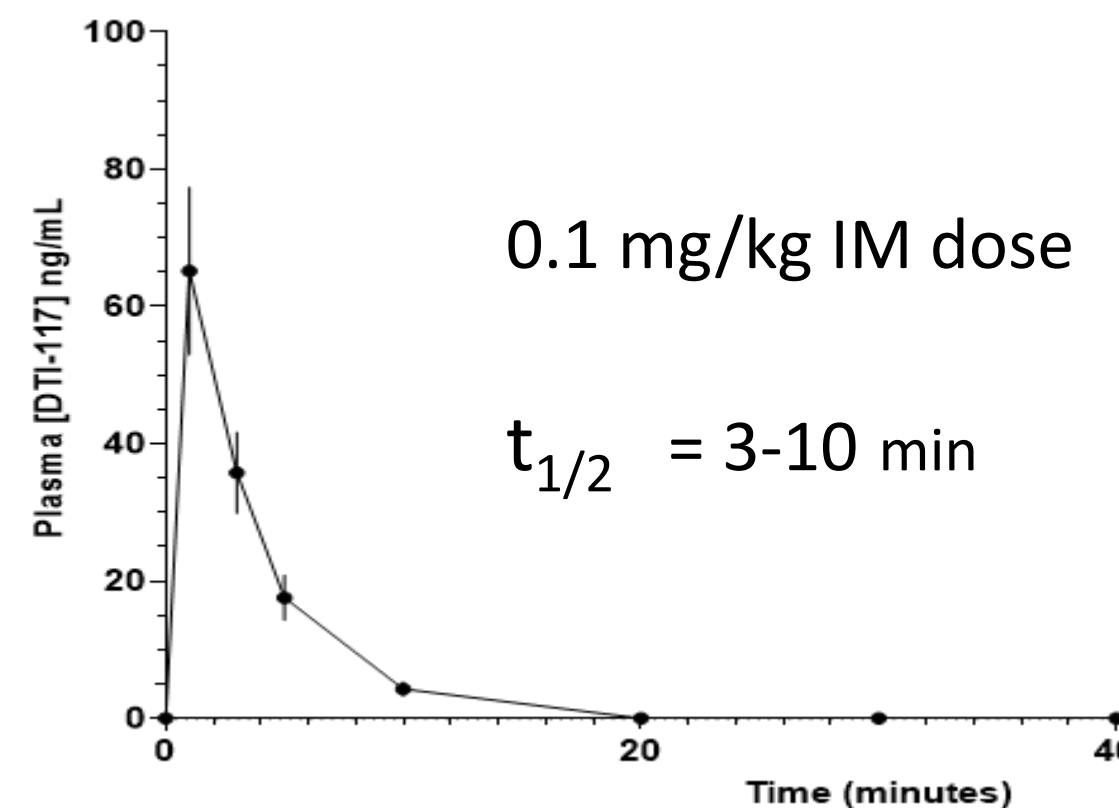


# DTI-117: ON-DEMAND DEFECATION

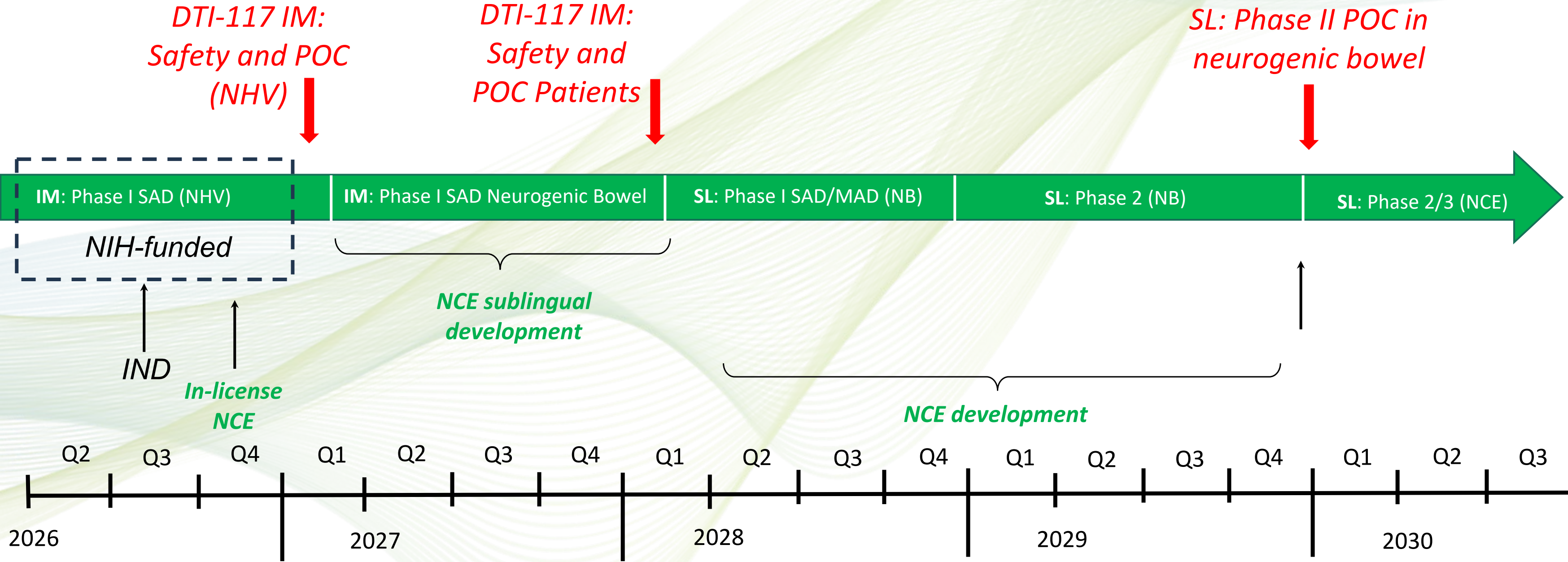
Dose-dependent defecation / urination in minipigs within 15 minutes



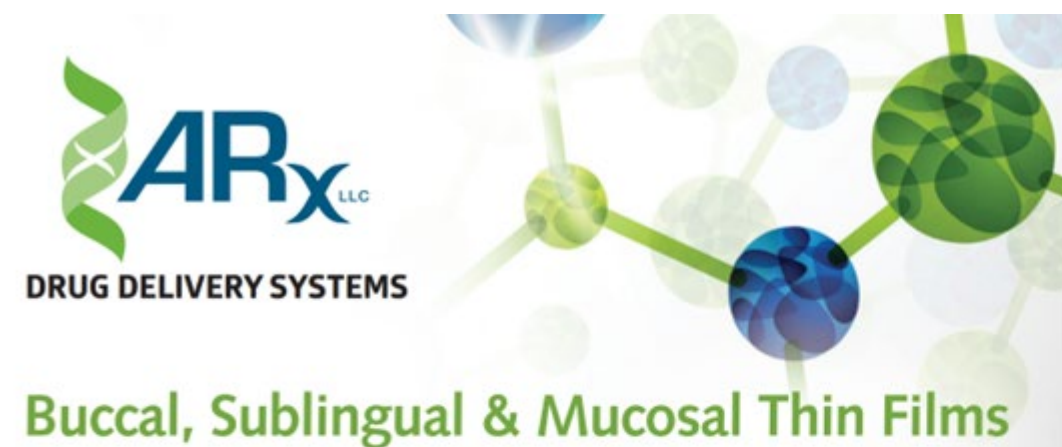
Rapid, transient absorption and clearance



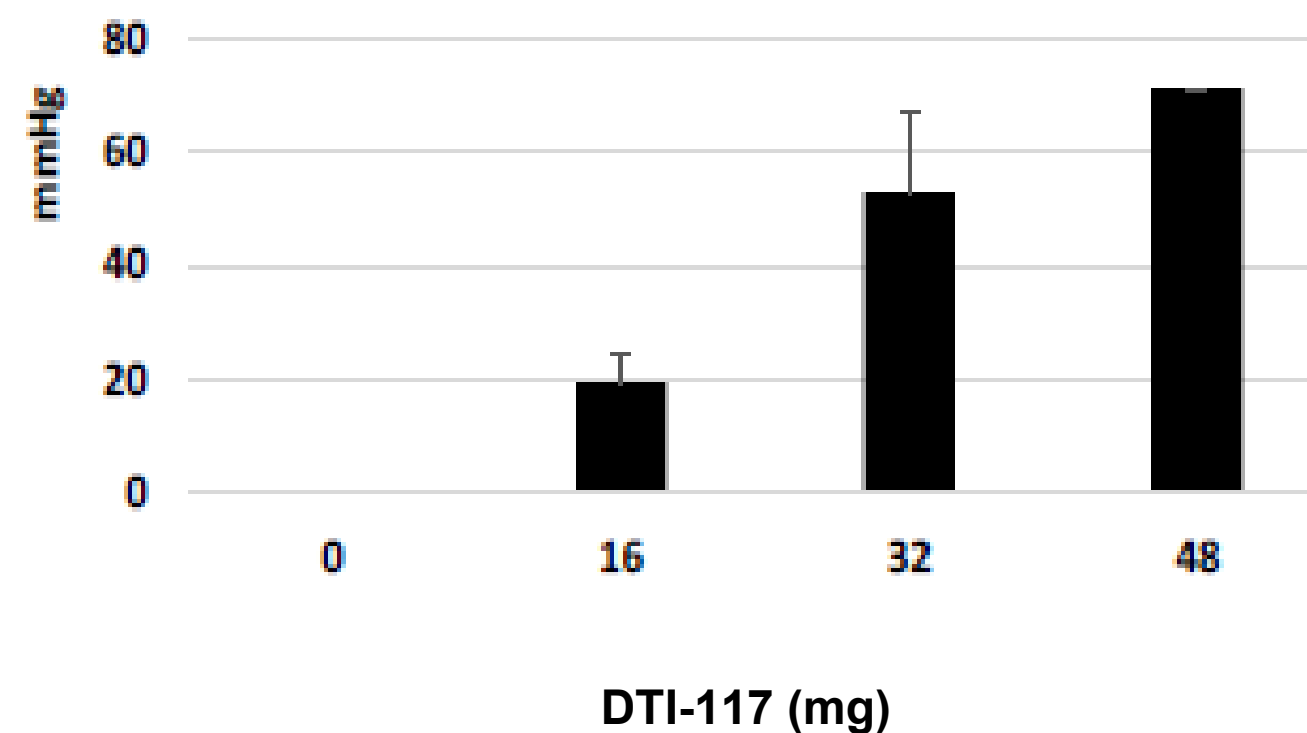
# DTI-117: Development timeline - 505(b)(1)



# DTI-117: Sublingual film dosing



Dose-dependent increase in colorectal pressure in anesthetized dogs



# DTI-301: Development timeline

Australia

*Begin Phase I*

*Safety and  
POC (NB)*

*Safety and  
Preliminary  
Efficacy (NB)*

*Safety and  
Confirmatory  
(NB)*

Phase I Study SAD | NBD

Phase I Study MAD | NBD

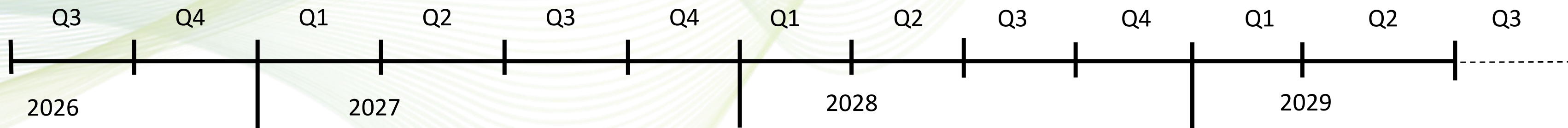
Registration Trial

US

*NCE*

*Repeated-dose tox studies*

*US registration*



## **Intellectual Property**

### **DTI 117**

- a. Method-of-use of NK2R agonists for on-demand voiding Issued in US, EP, JP, CA
- b. Composition-of-matter for DTI-100 analogs Filed/Issued in US only
- c. Composition-of-matter for DTI-117 analogs Filed in US, EP, JP, CA, AU
- d. In -license new COM patents for novel NK2R in process

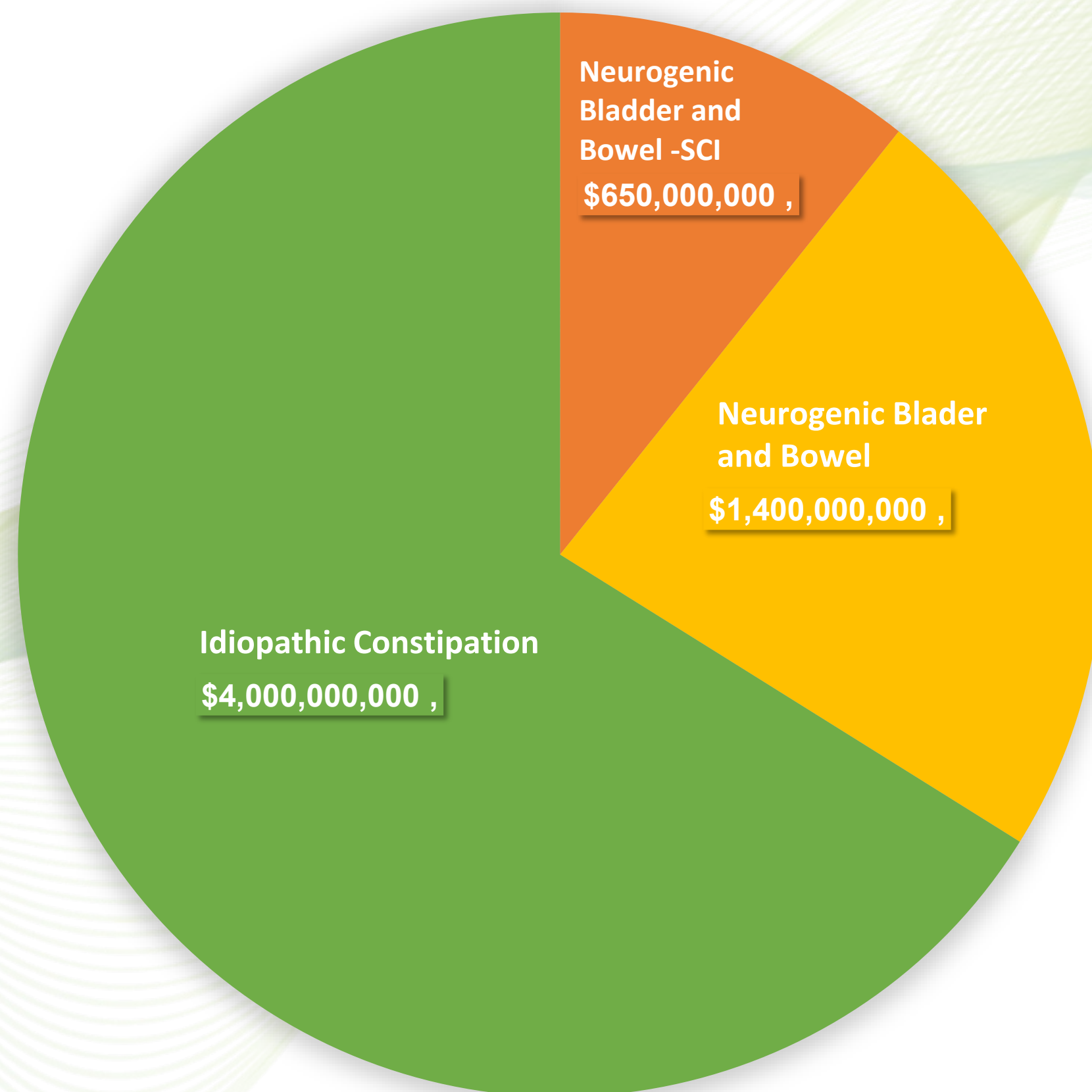
### **DTI 301**

- a. Method-of-use of capsaicin for on-demand defecation Issued in US, JP, AU
- b. Method-of-use of all TRPV1 agonists for on-demand defecation Filed in US, EP, JP, CA, AU
- c. In-license new COM patents for novel TRPV1 agonist in process

# Market Opportunity

| Indication                         | Population (US) |
|------------------------------------|-----------------|
| Idiopathic constipation            | 40M             |
| Neurogenic Bladder and Bowel       | 6.5M            |
| Neurogenic Bladder and Bowel - SCI | 250K            |

Price (\$6,500/yr)



A photograph of a healthcare professional, a woman in blue scrubs, smiling and pushing a wheelchair. An elderly man with a grey beard, wearing a plaid shirt and green pants, is seated in the wheelchair. In the background, other elderly people are seated at a table in a bright, indoor setting.

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

[ditonno@dignifytherapeutics.com](mailto:ditonno@dignifytherapeutics.com)