ELEVAIR™ Endobronchial Coil System

U.S. Food & Drug Administration
Anesthesiology and Respiratory Therapy Devices Panel
of the Medical Devices Advisory Committee

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PneumRx
a BTG International group company

ELEVAIR™ Endobronchial Coil System Introduction

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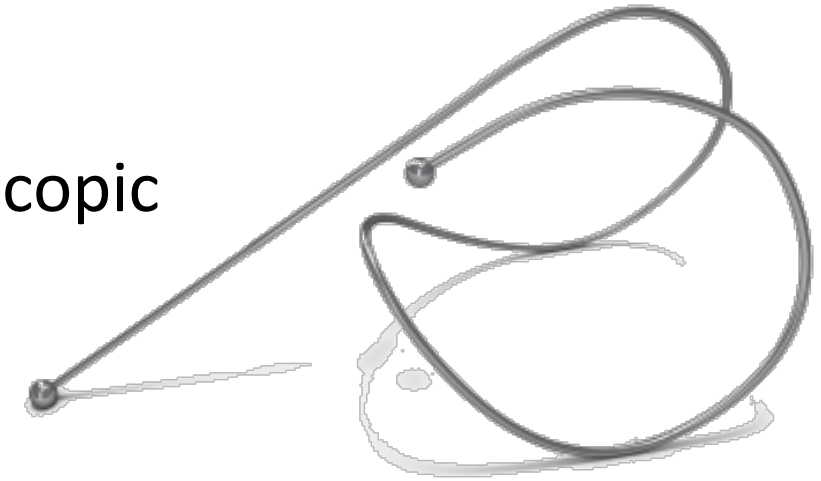
Unmet Need for Management of Severe Emphysema

- Emphysema is a progressive disease that results in significant debilitation
  - Approximately 3.5 million adults diagnosed in the US[a]
    - 1.2 million estimated to have severe emphysema[b]
- Patients with emphysema have increasing lack of mobility and limitations in activities of daily living
- The ELEVAIR™ System is intended for patients with significant symptom burden despite optimal medical therapy

[a] CDC FastStats: http://www.cdc.gov/nchs/fastats/default.htm. Accessed March 8, 2018.
[b] Tilert T, et al. *Respir Res*. 2013;14:103; Murphy DE and Panos RJ. *Int J Chron Obstruct Pulmon Dis*. 2013;8:199-208; Mapel DW, et al. *Int J Chron Obstruct Pulmon Dis*. 2011;6:573-581; Hurst JR, et al. *N Engl J Med*. 2010;363(12):1128-1138.

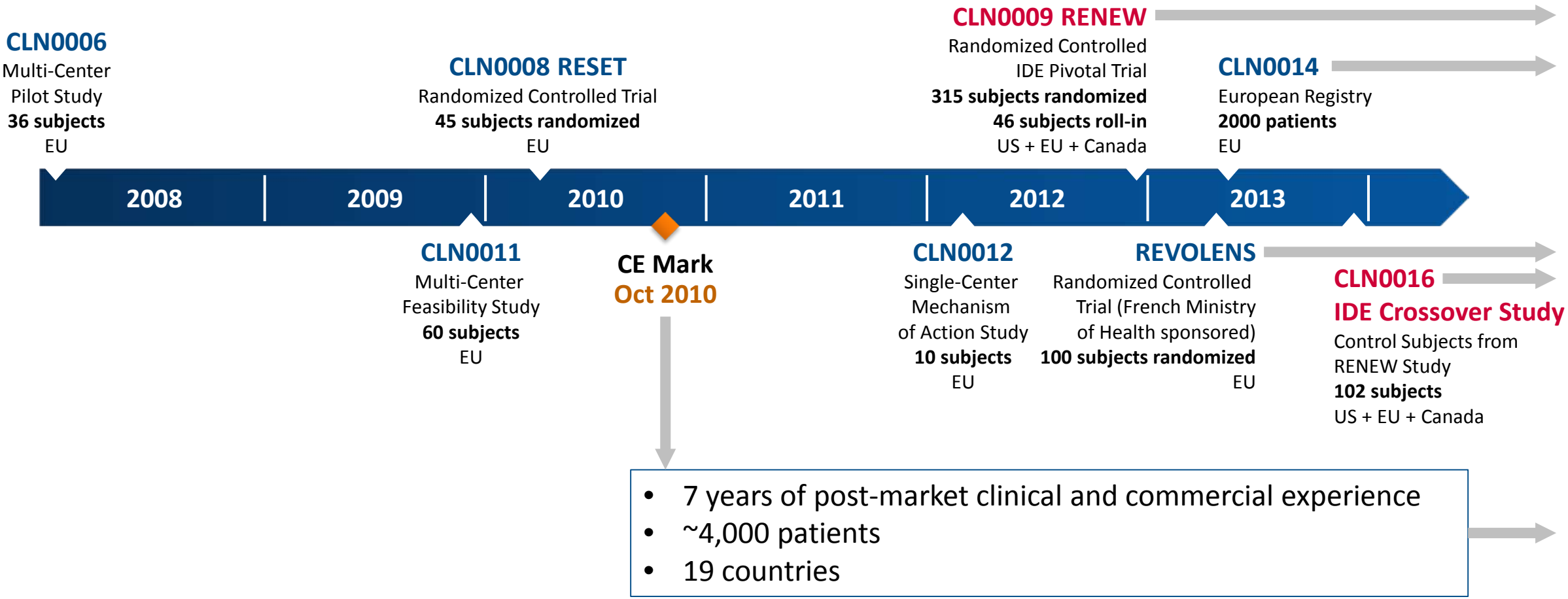
ELEVAIR™ Endobronchial Coil System Overview

- Designed to treat the specific pathophysiology of emphysema
  - Reduce lung hyperinflation, relieve breathlessness, and improve quality of life
- Device consists of Coils and a Delivery System
  - Coils: nitinol shape-memory implants
  - Delivery System: Minimally invasive, bronchoscopic



Coil

ELEVAIR™ System Clinical Development Program



Overview of IDE Clinical Program

RENEW

Randomized controlled trial
Treatment vs optimal medical therapy
12-month primary endpoint

RENEW Roll-in

First 2 subjects
at newly trained
clinical sites

Crossover

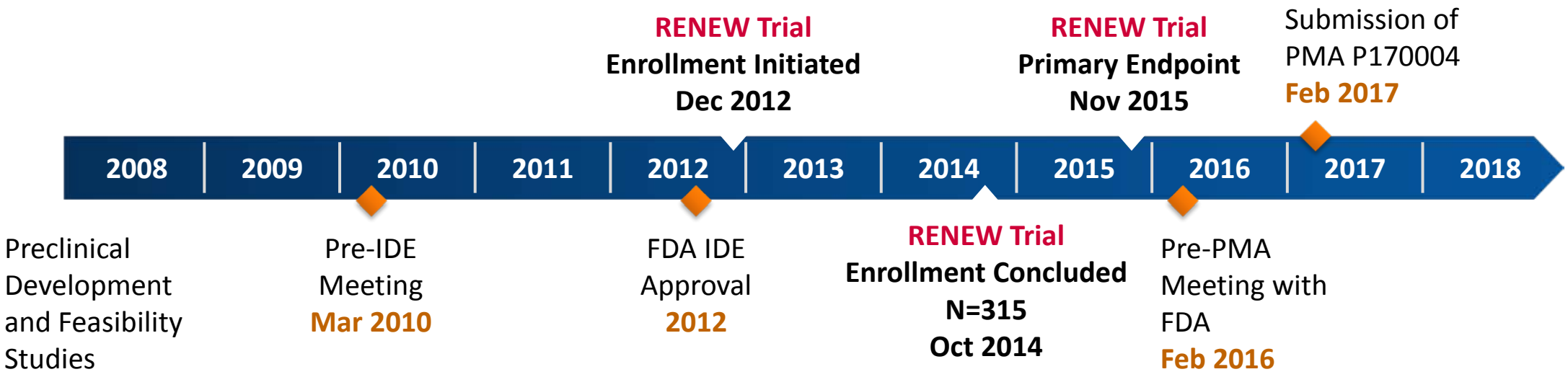
Eligible RENEW control
subjects receive
Coil treatment

Long-term clinical follow-up

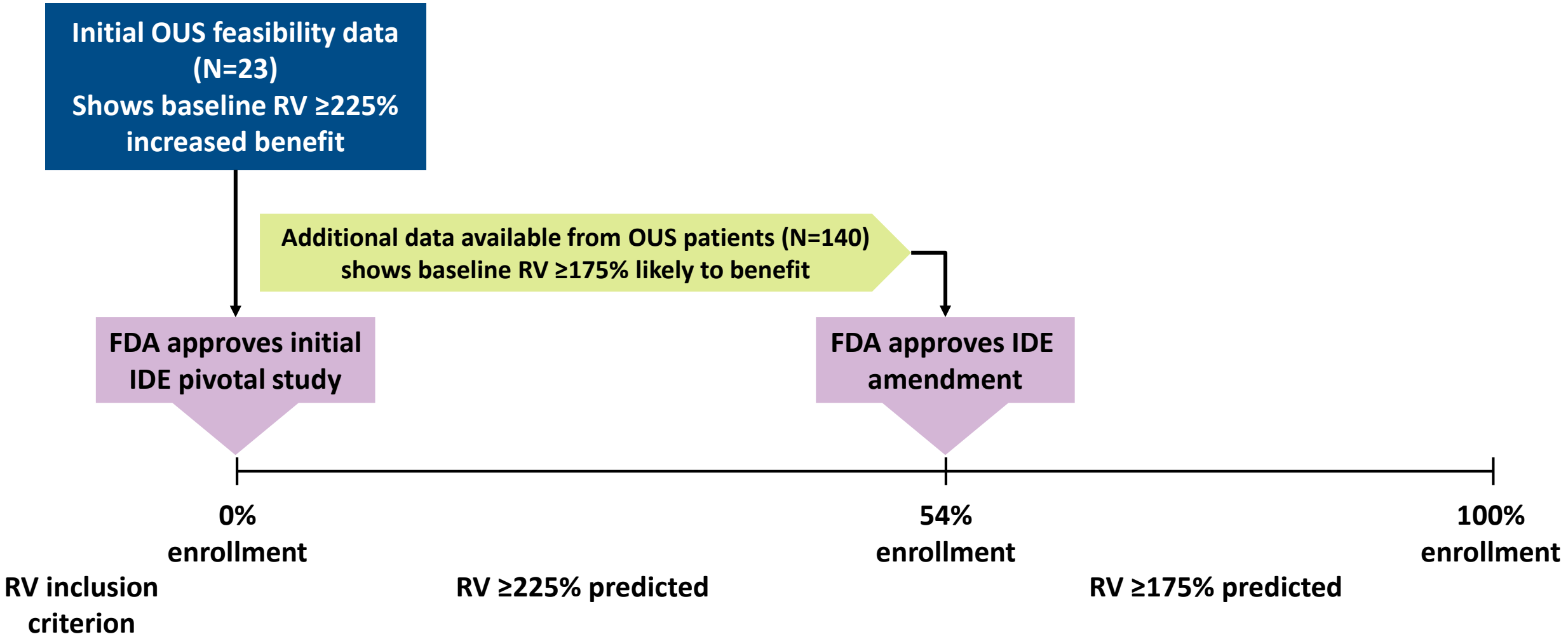
1 | 2 | 3 | 4 | 5

up to 5 years post-procedure for all Coil-treated subjects

FDA Interactions and PMA Regulatory Timeline



RENEW Protocol Amendment to Lower RV Threshold



Key Conclusions From Clinical Experience

- RENEW met all primary and secondary endpoints based on ITT population
- Greater clinical improvement seen across all endpoints in originally defined population with RV ≥225% predicted
- Totality of evidence demonstrates ELEVAIR™ System safety and effectiveness
  - Improves quality of life, exercise capacity, and lung function in patients with severe emphysema (heterogeneous or homogeneous) and severe hyperinflation (RV ≥225% predicted)
  - Manageable safety profile through 24 months after implantation
- Data demonstrate a favorable overall benefit-risk profile in the population with severe hyperinflation

Proposed Indications for Use

- The ELEVAIR™ Endobronchial Coil System is indicated for bronchoscopic placement of ELEVAIR Coils in patients with severe emphysema (homogeneous and/or heterogeneous) and severe hyperinflation to improve quality of life, lung function, and exercise capacity

Agenda

Emphysema Disease Background	**James Donohue, MD** UNC School of Medicine
RENEW Trial Design	**Claire Daugherty, MS** Director, Biostatistics, BTG International, Inc.
Development and Effectiveness	**Gerard J. Criner, MD** Founding Chair of Thoracic Medicine and Surgery, Temple University
Safety Profile	**David Hahn, MD** Head, PneumRx, Inc. University of Chicago, Pritzker School of Medicine
Post-Market Plan	**Julia Anastas, MPH** Vice President, Regulatory Affairs, PneumRx, Inc.
Patient Preference	**A. Brett Hauber, PhD** Vice President, Health Preference Assessment, RTI Health Solutions University of Washington, School of Pharmacy
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