Post-Market Plan

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PneumRx

a BTG International group company

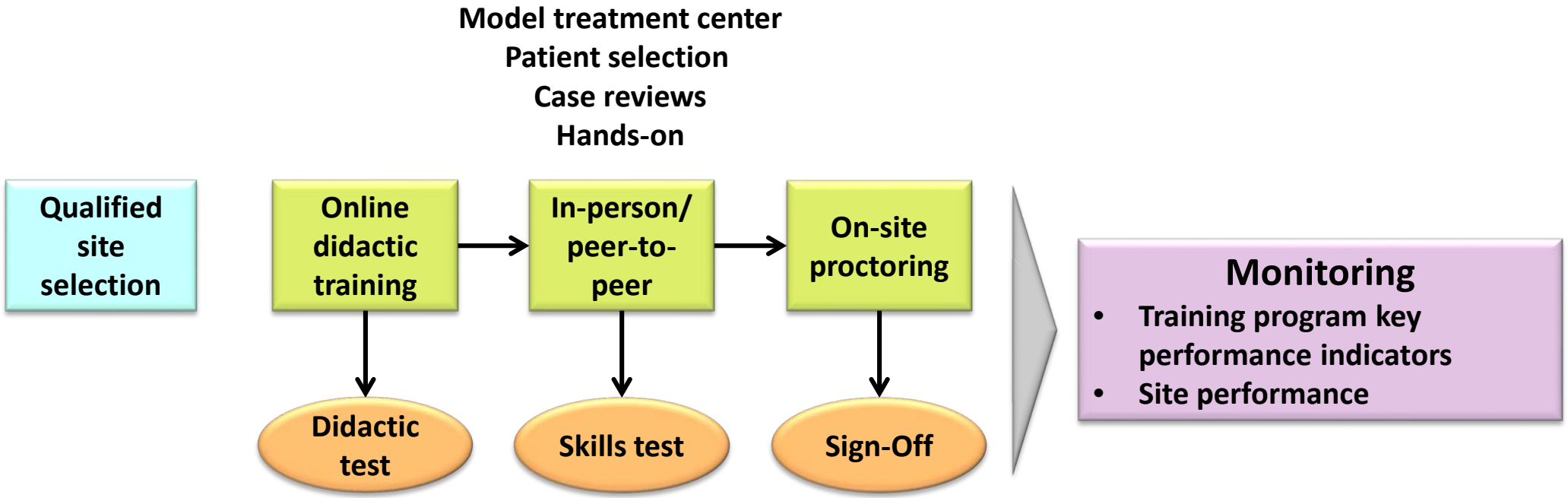
Post-Market Plan Elements

- Launch based on “Centers of Excellence” model
  - Treatment centers: offer therapy
  - Model treatment centers: offer therapy and host training program
- Comprehensive physician training program
  - Adapted based on post-market plan feedback
- Focused US post-approval study to collect additional safety and effectiveness data
- Ongoing European clinical study program and RENEW to collect long-term safety data
- Ongoing post-market surveillance program

Treatment Centers: Site Selection Criteria

- Hospitals have appropriate infrastructure, equipment, and personnel
- Sites and physicians have appropriate experience with interventional therapeutic procedures
- Sites and physicians commit to following PneumRx training curriculum and participating in US post-approval study
- Multidisciplinary approach to the treatment of patients with severe emphysema

Physician Training Program Concept



Focused US Post-Approval Study

- PneumRx Goal: capture a significant majority of all patients treated in US in first years of commercialization.

≥300 patients enrolled

Bilateral treatment

6- and 12-month follow-up

Follow-up annually up to 3 years

- **Endpoints evaluated at 12 months post baselines**
- **Proposed primary endpoint**
  - Δ SGRQ
- **Proposed secondary endpoints**
  - Δ PFT (FEV1, RV, RV/TLC)
  - Δ exercise capacity (6MWT)
- **Proposed primary safety endpoint**
  - Rate of device- or procedure-related respiratory SAEs of interest

Ongoing and Planned Clinical Studies

Study	Expected treated patients, n	Expected enrollment completion	Follow-up period/ visit schedule
US post-approval study (planned)	Minimum of 300	2021	3 yr/6 mo, annual thereafter
US IDE studies			
RENEW Randomized	158	2015	5 yr/Annual
RENEW Roll-in	46	2015	5 yr/Annual
Crossover	101	2016	5 yr/Annual
EU registry	Maximum of 2000	2020	3 yr/Annual
EU RCT (ELEVATE)	210	2019	2 yr/Annual

International Post-Market Surveillance Program Is Ongoing

- The Endobronchial Coil System has been commercially available since 2010 and has been sold in 19 countries
- Expand on post-market surveillance program for Europe
- Cross-functional Vigilance Team, with members from Vigilance, Clinical, Medical, Regulatory, and Quality, will review
  - Published literature
  - AE/SAE reports from commercial experience, long-term follow-up from US IDE program, European studies, and future US post-approval study
  - Ad hoc reviews of solicited requests for information from a variety of sources
- Contribute to development of clinical practice guidelines

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