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**Welcome!** We will be starting soon.

**PDMA Webcast**

Thursday, May 16, 2019, 1 PM ET / 12 PM CT

Incorporating Clinical & Consumer Discovery during Medical Device Product Development

**Sharon Baer**

Program Director, Advanced Innovation  
Sleep and Respiratory Care Division of  
Philips

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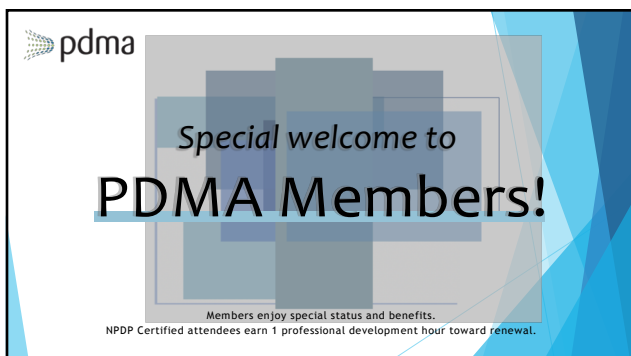
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JPIM - Journal of Product  
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November 2-5, 2019

Save the Date! 2019

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# Upcoming Events



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Keynote  
**DR. JEFF COVIN**  
Professor of Entrepreneurship  
Indiana University  
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# Clinical Discovery & Medical Device Product Development

Sharon Baer  
Program Director  
Advanced Innovation, Sleep and Respiratory Care  
Philips Healthcare

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# Agenda

- ▶ 4 P's
- ▶ Customer vs. Patient
- ▶ Clinician's role
- ▶ Provider
- ▶ Coverage & Payment
- ▶ Approval Process



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### 4 P's of Medical Device Product Development

- ▶ Patients
- ▶ Physicians
- ▶ Payers
- ▶ Providers
  
- ▶ Approval by Government Agency

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### Medical Device Industry

*The Use Case of the Device by Patients and other key stakeholders is critical*  
*They are end consumer of the product*




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### Needs Exploration in Medical Device Industry

#### ▶ Many ways to explore customer needs

##### ▶ Qualitative Research

- ▶ In Depth Interviews
- ▶ Ethnography
- ▶ Delphi Groups
- ▶ Social Listening
- ▶ Focus groups



##### ▶ Quantitative Research

- ▶ Validation of needs in a larger cohort
- ▶ Segmentation
- ▶ Target Consumer for product




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## Concept Exploration for Patients

- ▶ Explore to understand current state
  - ▶ Person vs. Patient
- ▶ What are current challenges
  - ▶ observed
  - ▶ stated
- ▶ What are current methods they use to remove the challenges/barriers
  - ▶ how satisfied are they
- ▶ What are other methods/ideas could be used to remove these barriers




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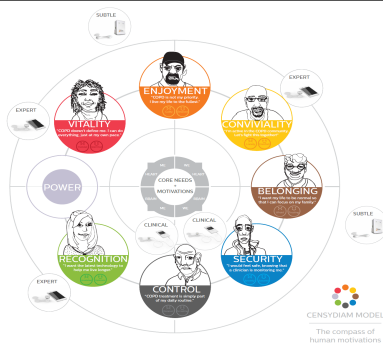
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## Physician Roles in Product Development

- ▶ Ethnography or In Depth Interviews about current practice
  - ▶ GAP or Needs analysis
- ▶ Subject Matter Expert
- ▶ Scientific Advisory Board
  - ▶ Design of clinical trials and expected outcomes
  - ▶ Review of evidence
  - ▶ Publication or Evidence Creation
- ▶ Idea owner/Patient Owner/Major Stakeholder
  - ▶ Key in product development




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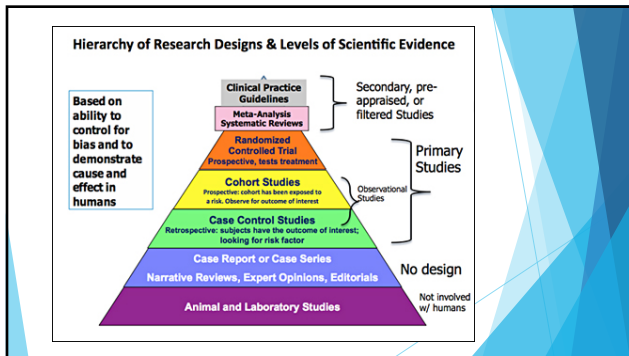
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**Clinician Role vs. Patient Role**

<p>► Patient</p> <ul style="list-style-type: none"> <li>► Target customer for use of product</li> <li>► Remove identified "Pains" from previous or current product</li> <li>► Target population and use case</li> <li>► Intended vs. unintended use</li> <li>► Description of who can use and who cannot use</li> <li>► FDA approval pathway</li> </ul>	<p>► Clinician</p> <ul style="list-style-type: none"> <li>► Clinical Evidence to support intended use</li> <li>► Benefit of product application vs. current treatment regimen</li> <li>► Prescription requirements for ordering</li> <li>► Intended use</li> <li>► Off Label use</li> </ul>
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**Provider or Distributor of Medical Product**

- Intermediary or distributor to end consumer
- Pharmacy, durable medical provider, Retailer or Big Box store, On-line
- Improvements in product development maybe to aid distributor
  - Cost effective or time savings
  - One Box Bundled set up
  - One touch delivery
  - Improving Distribution methods

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## Payer for the Product

- ▶ Reimbursed vs. Over the Counter (OTC)
- ▶ Every country has different ways to reimburse
- ▶ Payer Coding scheme's
  - ▶ HCPCS
  - ▶ CPT
  - ▶ ICD 10
- ▶ Coverage
  - ▶ Medicare
  - ▶ Medicaid
  - ▶ Local and National Coverage: LCD
- ▶ Reimbursement/Payment
  - ▶ Payment




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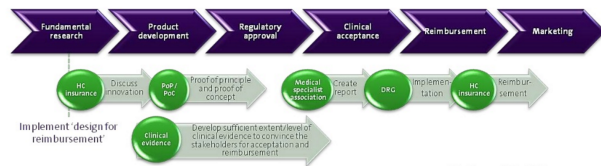
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## Design for reimbursement



Shifting development from linear process to parallel process

Frontloading important steps to estimate the chances of success or failure




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## Summary

- ▶ Medical Device companies need to take into account a variety of stakeholders when developing a product
- ▶ Innovation can be for any of the key stakeholders
- ▶ A variety of testing and validation methods can and should be used when developing new solutions for medical conditions

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# Questions?

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Sharon Baer

Thank you for joining us!

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Program Director, Advanced Innovation, Sleep and Respiratory Care Division of Philips

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• **Wayne Fisher** •  
President and Founder, Rockdale  
Innovation

# Join us in June!

## PDMA Webcast

Thursday, June, 2019, 1 PM ET / 12 PM CT

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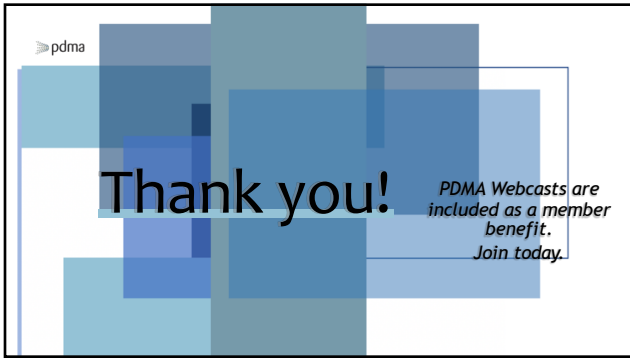
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