

DESIGN WITH THE END IN MIND

PRESENTED BY:

DEBBIE GARNER

Co-CEO, FEMSelect Ltd.



My name is **Debbie Garner**
*and a few words about my background in
market access*

01 I have over **20 years of experience** as an executive in the healthcare space, focusing on the commercialization of drugs, devices and HCIT.

02 Some key high points:

- At Eli Lilly, I led a team responsible for **over \$25M in annual sales despite market access challenges**
- Designed and executed a new product launch strategy that **achieved reimbursement in the Israeli health basket**
- As EMEA Regional Director for Avalere Health, I **focused on reimbursement strategies for start-ups.**

03 Today, I'm **Co-CEO of FEMSelect**, a women's health medical device company where I received a HCPCS reimbursement code from CMS for our device.



FEMSELECT SUMMARY

CLEARED BY FDA
+ CE MARKED



ENPLACE®
COMPELLING
BRAND

INNOVATIVE
DEVICE



MINIMALLY
INVASIVE

\$4B
US MARKET



TARGET
MARKET

IP
PORTFOLIO



4 PATENT
FAMILIES

CLINICAL &
MARKET
ACCEPTANCE



EVIDENCE BASED
MEDICINE

30 – 50% of women are affected by Pelvic Organ Prolapse

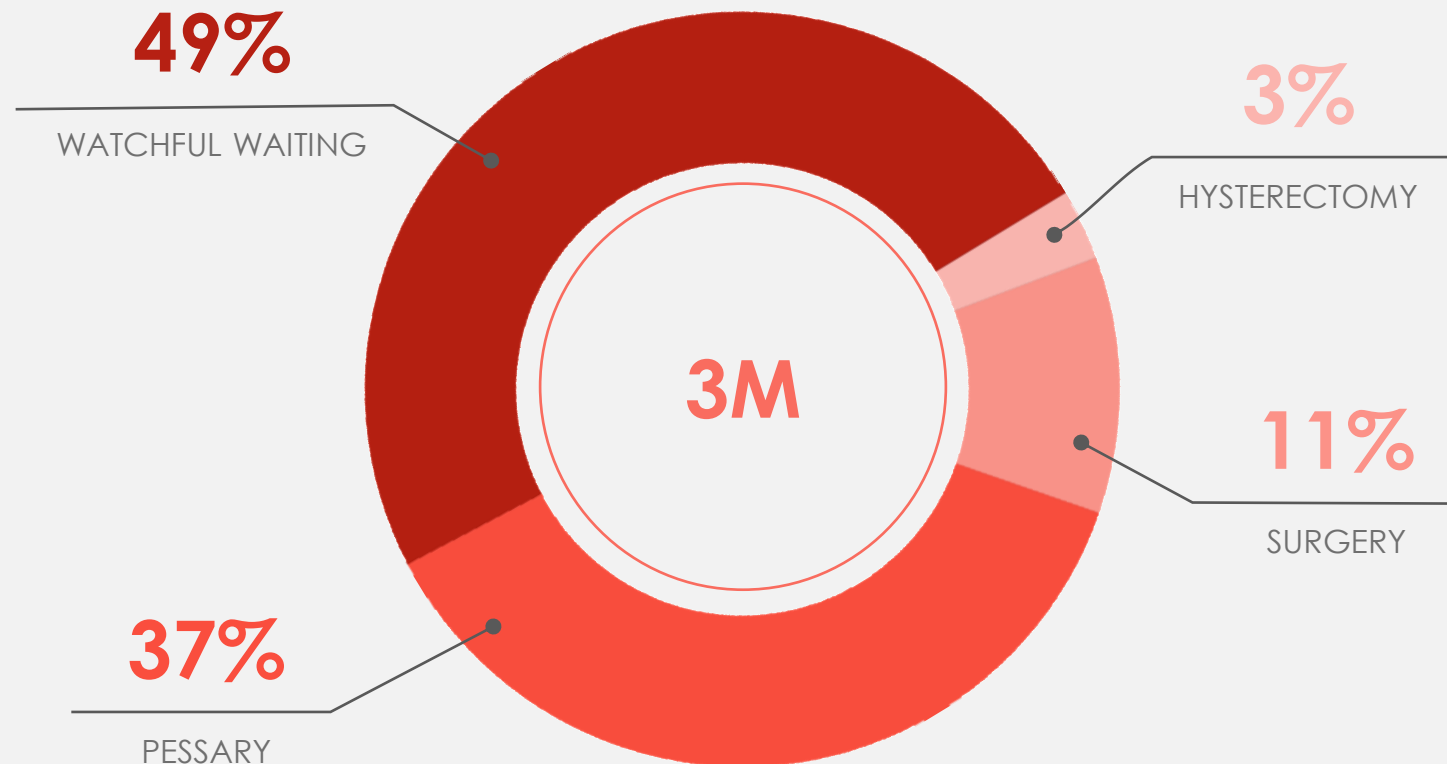


Pelvic Organ Prolapse is a painful condition that occurs when the normal support of the vagina is lost, resulting in sagging of the female pelvic organs.

LIFE-ALTERING SYMPTOMS:

- ▶ Incontinence
- ▶ Pain
- ▶ Inability to participate in normal physical activity
- ▶ Pulling or heavy pelvic sensation
- ▶ Feeling of sitting on a ball
- ▶ Difficulty with sexual intercourse
- ▶ Constipation/Difficulty passing stool

LIMITED OPTIONS FOR **3 MILLION**³ WOMEN DIAGNOSED WITH PROLAPSE



THE ONLY TRULY MINIMALLY INVASIVE APPROACH

- ▶ Minimal dissection – vaginal approach
- ▶ NO mesh implant
- ▶ QUICK (1-2 days) return to activities vs. 6-12 weeks SOC
- ▶ 4 year data showing durable repair and minimal AE's ⁵
- ▶ Cleared by FDA / CE Mark



4mm wide
10x shorter than an IUD
6x smaller than the diameter of a dime



BUILD PRODUCT AROUND CUSTOMER/PAYOR NEEDS (NOT JUST PATIENT)

WHEN DO I START?

DAY ONE, just as you would for clinical/IP/regulatory work

HOW DO I PREPARE FOR PAYMENT?

UNDERSTAND your customer

CONSIDER customer (payor) needs during product development

TAILOR clinicals/regulatory/R&D to payor needs



DESIGN WITH END IN MIND: MARKET ACCESS



Payors require specific types of data in order to make a decision.

01

WHAT TO COLLECT

CLINICAL ENDPOINTS

ECONOMIC DATA

COSTS + MISC INFO

EVIDENCE NEEDED
FOR REIMBURSEMENT

02

TIPS FOR GATHERING INFORMATION

- **Start on Day One**

Create your business plan around a customer

- **Hire a strong reimbursement consultant** or market access headcount (just as you would for regulatory processes)

- **Conduct Payor interviews around TPP** (target product profile) can even be anonymous if you are in stealth phase

- **Talk to OR services contacts/clinicians who sit on CPT** and other reimbursement committees

- **Invite a payor to sit at FDA meetings**





KEY CONSIDERATIONS

PATIENT DEMOGRAPHICS

AGE

GENDER

HEALTH STATUS

INSURANCE TYPE

SETTING OF CARE

WHO IS YOUR CUSTOMER, AND WHY?

PAYOR

PROVIDER

CONSUMER

HOSPITAL

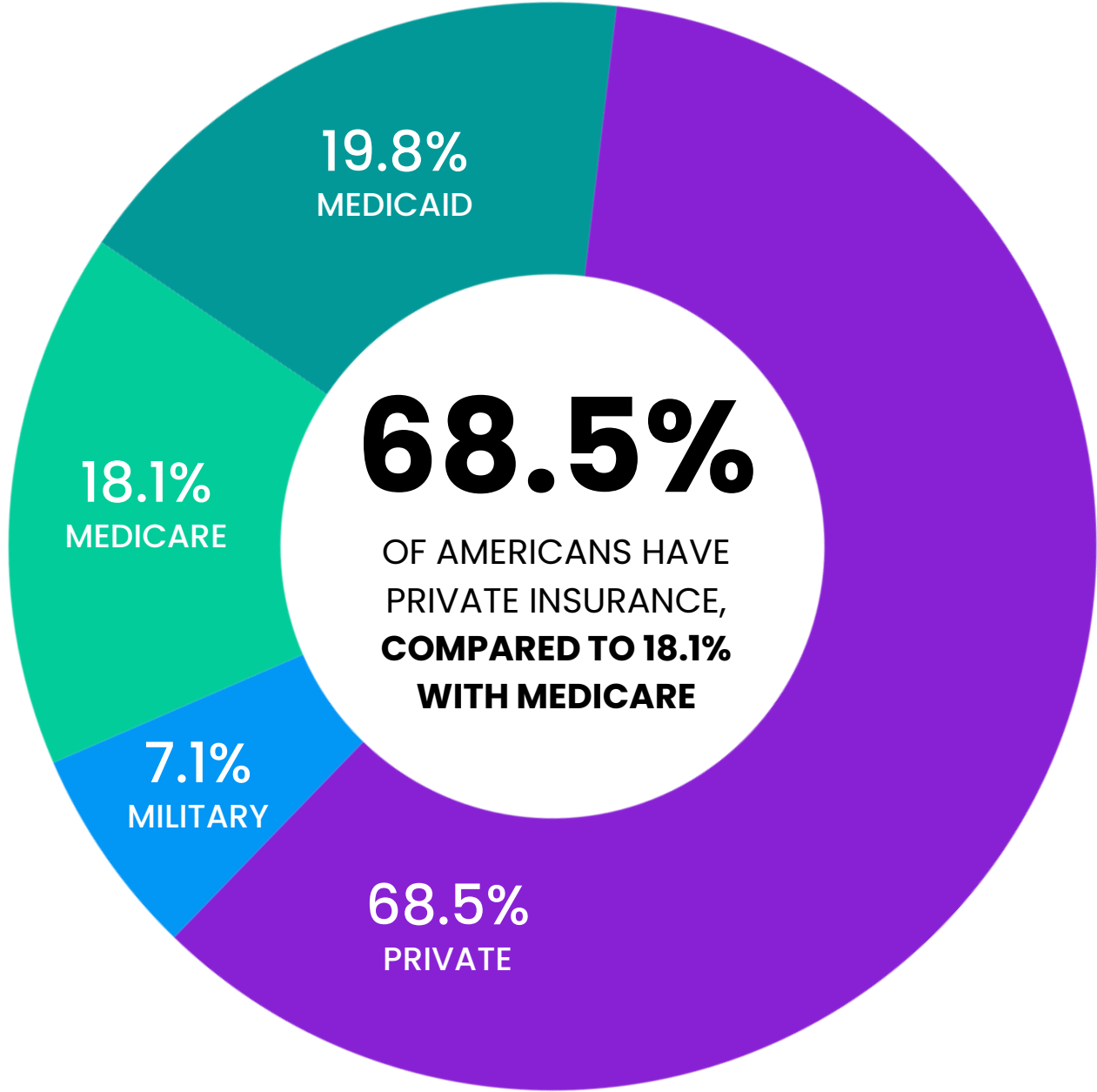
CMS

COMMERCIAL

ACCOUNTABLE CARE ORG

WHAT ARE YOUR CUSTOMER'S INTERESTS/INCENTIVES/MOTIVATIONS?

AMERICAN MEDICAL CARE COVERAGE BY INSURANCE TYPE



Source: U.S. Census Bureau, Table HIC-4_ACS. Health Insurance Coverage Status and Type of Coverage by State-All Persons: 2008 to 2019, September 2020. Notes: Italicized = does not add to total. Individuals may have more than one type of coverage at a time (for example, Medicare and Medicaid).



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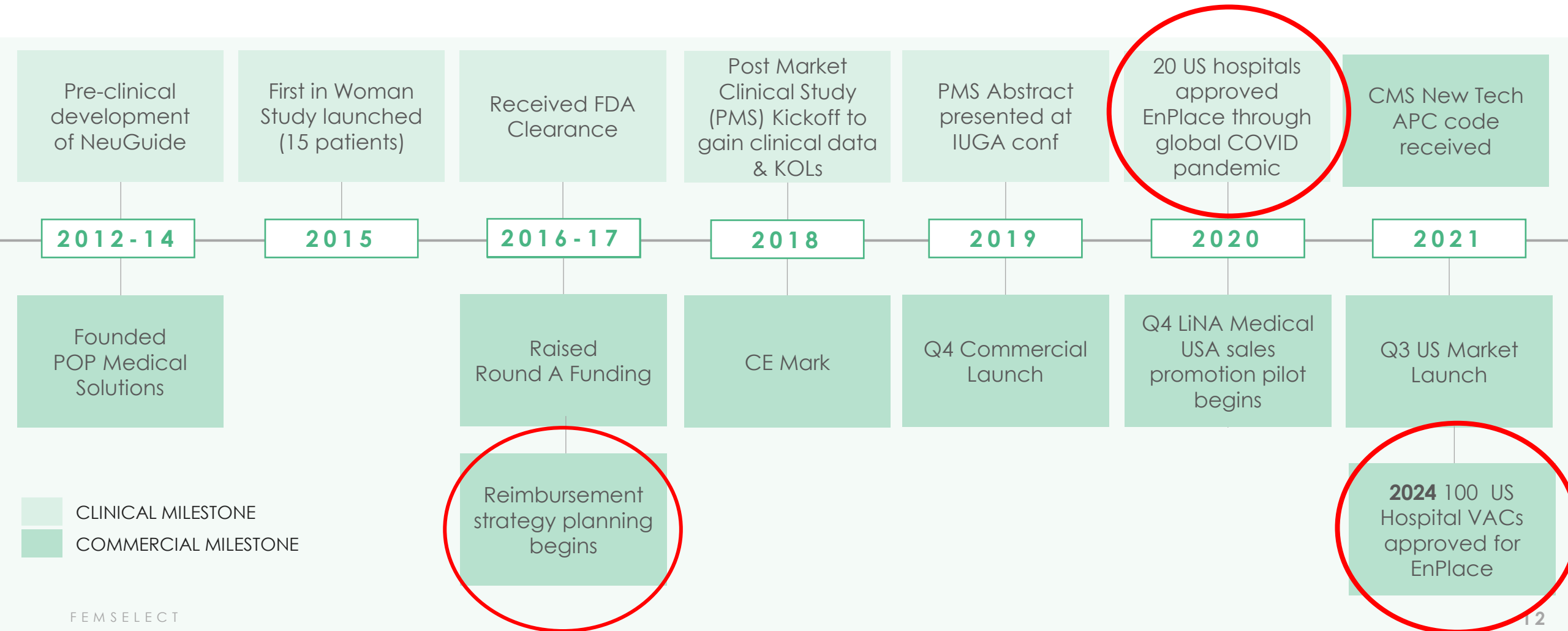
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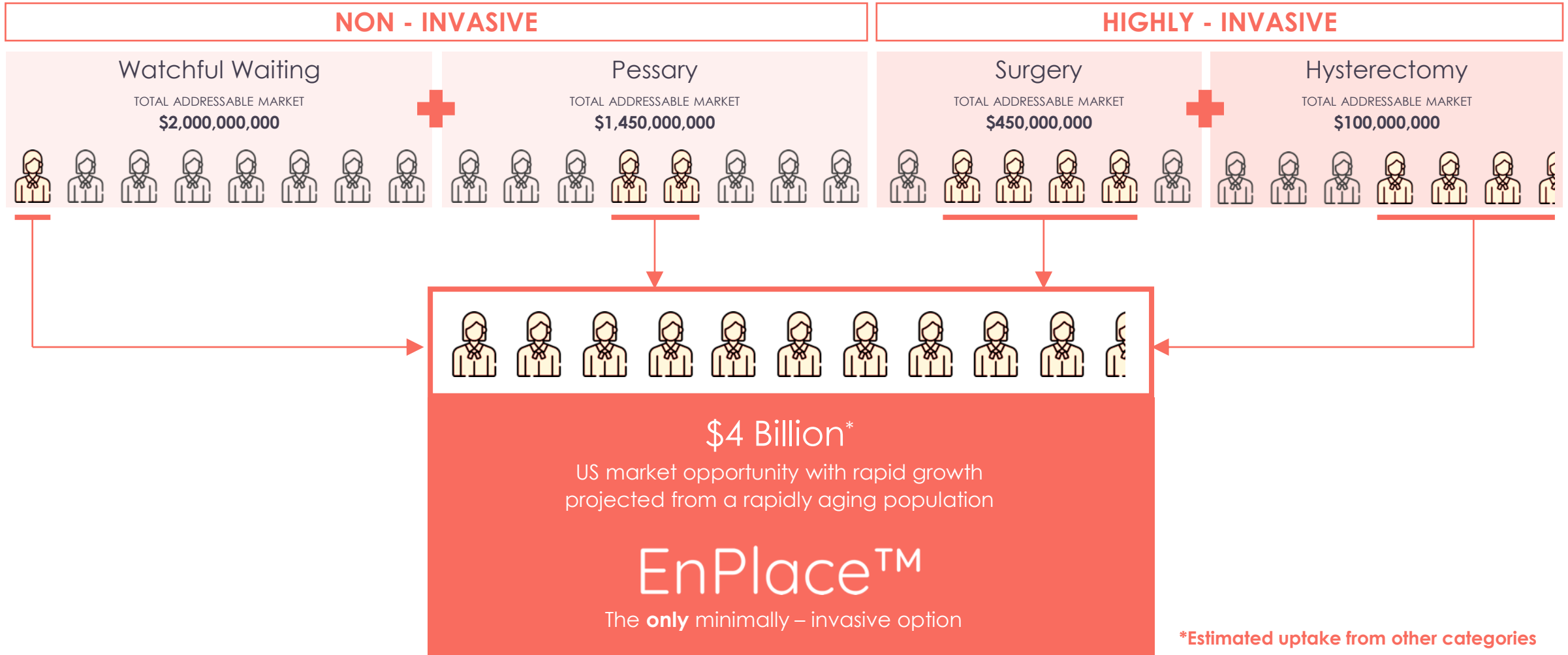
ACCOUNTABLE CARE ORG

WHAT ARE YOUR CUSTOMER'S INTERESTS/INCENTIVES/MOTIVATIONS?

FEMSELECT HISTORY



A **NEW** MARKET OPPORTUNITY⁴





PAYMENT MODELS



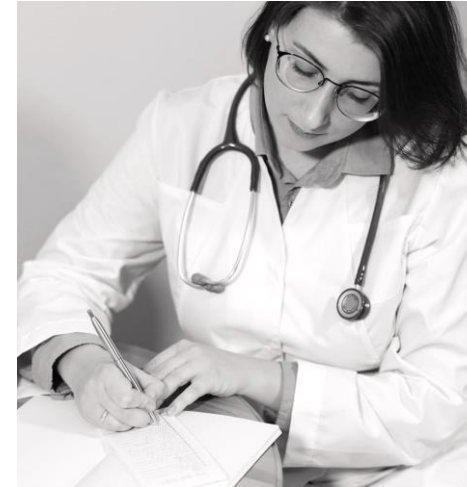
PAYOR REIMBURSEMENT

- CMS
- Commercial
- Accountable Care Organization
- Population health management or Pilot agreement



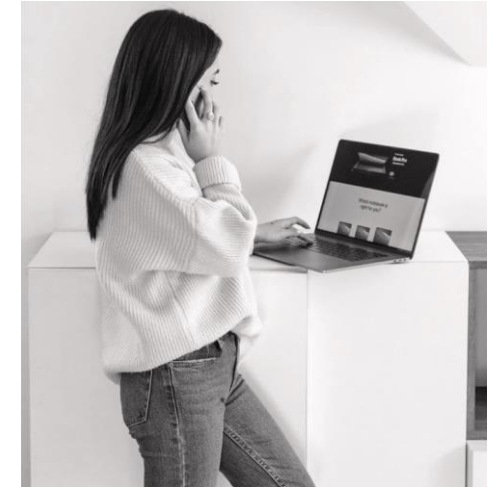
DIRECT TO HOSPITAL

- Hospital DRG payment
- Hospital APC payment
- With reimbursement from payor or without



DIRECT TO PROVIDER

- Physician Practice Buy & Bill



DIRECT TO CONSUMER

- Sell to pharmacy
- Online sales

TECHNOLOGY ACQUISITION PROCESS

Hospitals consider a variety of information sources when evaluating a technology.

Hospital administrators are interested in a wide variety of data sources. Providers and industry representatives may be the initial sources of information and should supply:

COMMONLY REQUESTED DATA

PATIENT POPULATION

REQUIRED TRAINING

PRODUCT ORDER SHEET

CLINICAL EDUCATION

FDA CLEARANCE / APPROVAL

TAXPAYER ID

STUDIES/PUBLICATIONS

PHYSICAL PRODUCT REQUIREMENTS

CODING INFO

COMMONLY REQUESTED NON-FDA DATA

SOCIETY GUIDELINES

CLINICAL POPULATION INFO

COST-BENEFIT ANALYSIS

QUALITY ASSURANCE PLANS

REIMBURSEMENT

PATIENT POPULATION INFO

CLINICAL EVIDENCE

TECHNOLOGY ASSESSMENTS (3RD PARTY, E.G., HAYES, ECRI, NICE, ETC.)



TECHNOLOGY ACQUISITION PROCESS



CLINICAL CONSIDERATIONS

COST CONSIDERATIONS



Physician identifies potential technology

- ### TECHNOLOGY-SPECIFIC INPUTS
- Cost benefit analysis
 - Reimbursement
 - Clinical summary
 - Assessments
 - Technology
 - Internal/External



Technology brought to Hospital Administrator or Department Head



Hospital makes a decision on the technology

- ### HOSPITAL-SPECIFIC INPUTS
- Certificate of need
 - Required training
 - Clinical Education
 - Patient population
 - Physical considerations



Hospital committee meetings and internal staff review



FDA + REIMBURSEMENT

**01**

INFLUENCE OF FDA WORK ON REIMBURSEMENT PATHWAY:

- **Type of Clearance** and **Indication for Use** can influence coverage
- IFU can potentially bucket you into a certain procedure
- Payors - can decide differently from CMS

02

LEVERAGING FDA PROCESS FOR POSITIVE REIMBURSEMENT:

- **Breakthrough Device Program**
Can potentially give higher payment in certain circumstances, although not certain
- **Parallel Review Program**
Not many technologies have been approved through this program
- **Invite Payors into Pre-sub Meeting**
For feedback on what they want to see for medically necessary





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THANK YOU

