

## MoxHealth

Molecular Diagnostic Solutions for Urologic Cancer

VFB Expert Tips Day, Flanders Expo 30 September 2017

Presented by:

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#### Our Mission

# Improve patient outcomes by delivering molecular diagnostic solutions for urologic cancers

#### Areas of Focus

Prostate Cancer



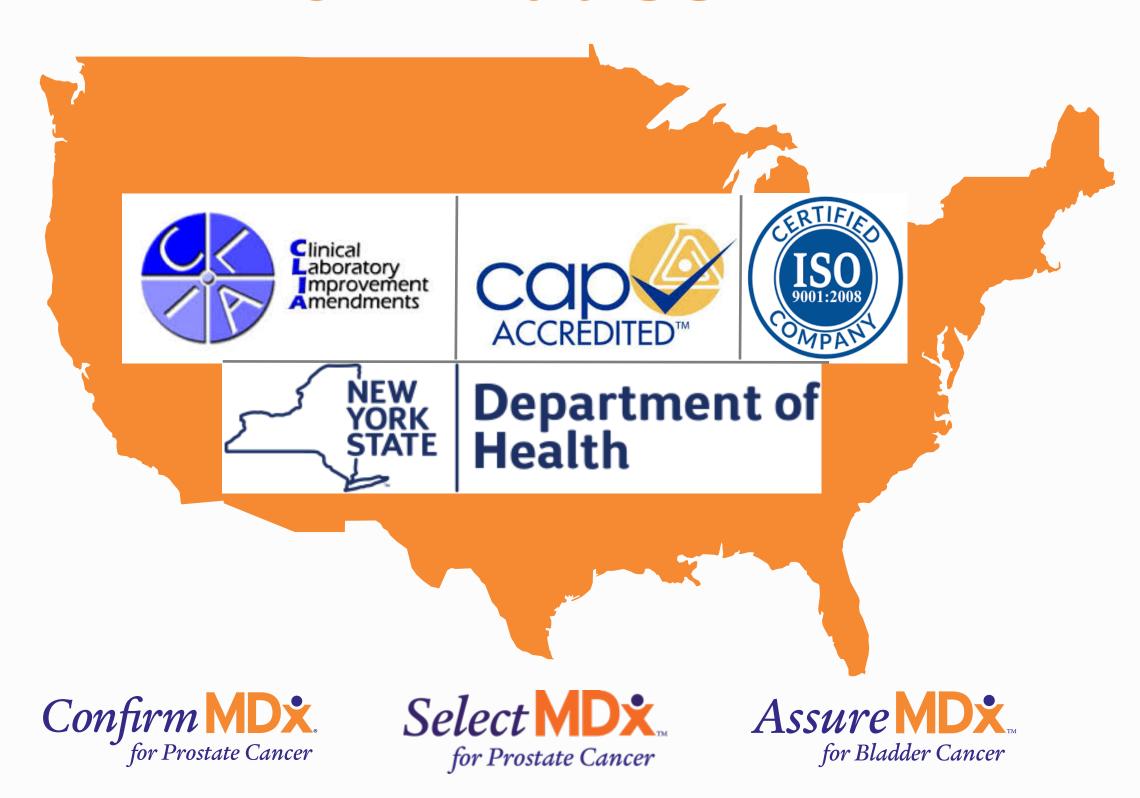
Bladder Cancer





### Commercial strategy overview

#### CLIA Lab US



- Laboratory developed test (LDT)
- Large national sales force 50 reps
- Reimbursement Medicare & commercial
- Included in the NCCN guidelines



- CE-marked in-vitro diagnostic (IVD) kits
- Direct sales 5 reps
- Distributors



Achievements

Steps

# Broad coverage in the US has laid the groundwork to accelerate adoption of ConfirmMDx

#### Commercial

- √ 60+ payor contracts incl. Kaiser
- ✓ NCCN guidelines
- ✓ CPT code awarded

#### Medicare

- ✓ LCD issued 2014
- √ 8,000+ registry patients
- √ First test under MoIDX

#### Government

- ✓ GSA contract awarded
- ✓ 8 VA hospitals signedup under the GSA
  contract

- ☐ Increase payor contracts
- ☐ AUA guideline inclusion
- ☐ Complete new studies\*
  - PRIORITY
  - CARIBOU
- ☐ Continue Medicare registry

- ☐ Sign-up remaining146 VA hospitals
- Increase testingvolumes withincontracted hospitals



<sup>\*</sup> New studies expected to replace PASCUAL clinical study data for consideration under MoIDX LCD.

## SelectMDx is gaining traction worldwide

#### US

√ 13 payor contracts

#### Europe

- √ 6 distribution agreements
- ✓ First CE-marked IVD kit adopted in Germany

#### ROW

√ 4 distribution agreements

Achievements

Keys/Next Steps

- ☐ Increase payor contracts
- □ NCCN & AUA guideline inclusion
- □ CPT code

- ☐ Increase IVD Kit
  distribution agreements
- Increase testingvolumes

- ☐ Increase distribution agreements
- Increase testingvolumes



## Research collaborations support our pipeline:



Leverage individual gene discovery platforms to jointly validate new urologic, colon and lung cancer biomarkers



Validate licensed MISH visualization technology in current and future bladder and prostate cancer liquid biopsy tests





Develop sample in and result out based platforms for future kidney cancer (epi)geneticbased assays



## H1 2017 financial highlights

~15K patients tested

Growth compared to H1 2016

+44%

\$24.3M total revenue

+87%

\$0.6M operating

profit

+\$8.1M

\$1.4M EBITDA

+\$8.1M

Cash collection

increase

+31%



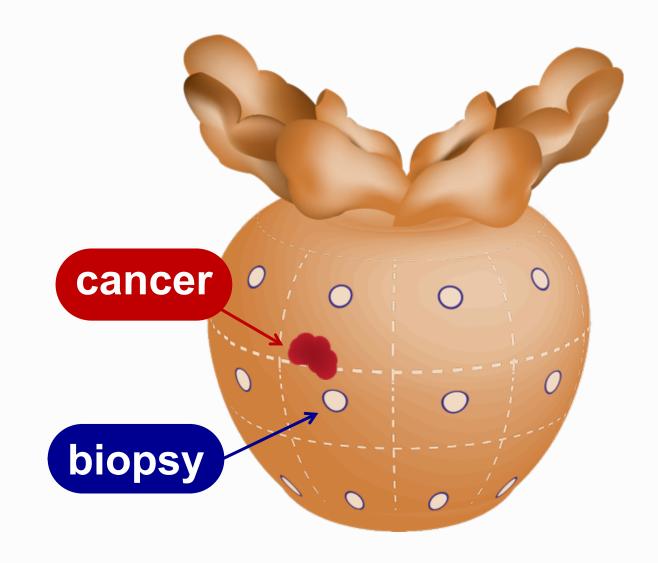
## Prostate cancer diagnosis standard of care

Prostate cancer is the 2nd most common cancer diagnosed in men globally with over 2M biopsies conducted annually in the US & Europe<sup>2,3</sup>

**Procedure** 



**Sampling Challenge** 



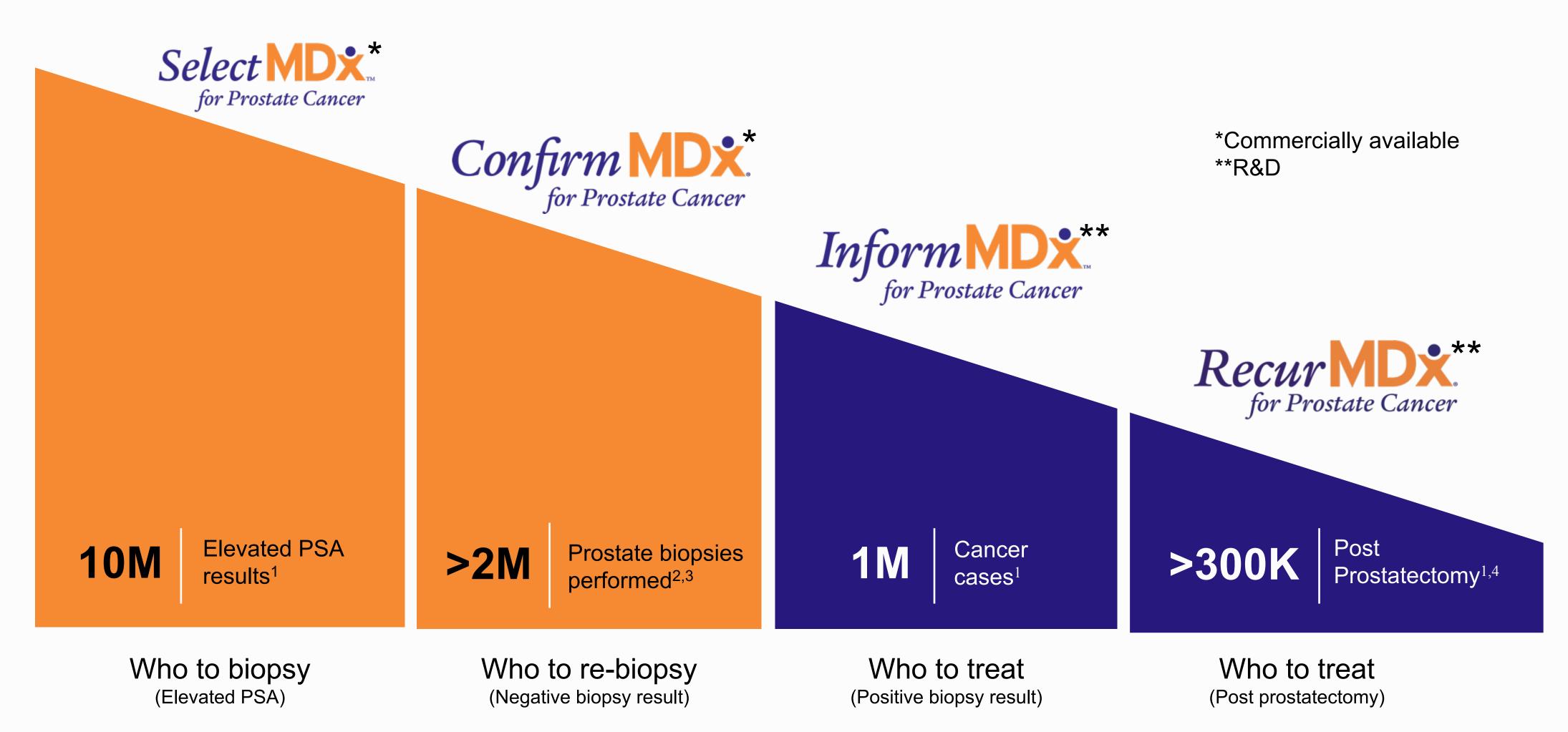
Histopathology





### Our global prostate cancer portfolio vision

MDxHealth diagnostics becomes the standard of care in prostate cancer



<sup>1.</sup> Company's estimation 2017 based on Ferlay J, et al. GLOBOCAN 2012 v1.1, Cancer Incidence and Mortality Worldwide; 2. MRC Clinical Trials Unit at UCL. PROMIS shows MRI scan could help a quarter of men safely avoid prostate biopsy. 2017; 3. Crawford D,et al. (2017) *J Pros Canc* 2:1 . 4. Paller C, et al (2013) Clin Adv Hematol Oncol 11(1): 14–23. (30% calculation based on global incidence from GLOBOCAN)



## Valuable tissue biopsy test for physicians and patients

MDxHealth lead product





Avoid unnecessary repeat biopsies



#### **The Product**

- Proprietary tissue biopsy PCR DNA test
- NPV 96% for high-grade prostate cancer



#### The Urologist

- Provides actionable information
- In the NCCN guidelines



#### **The Patient**

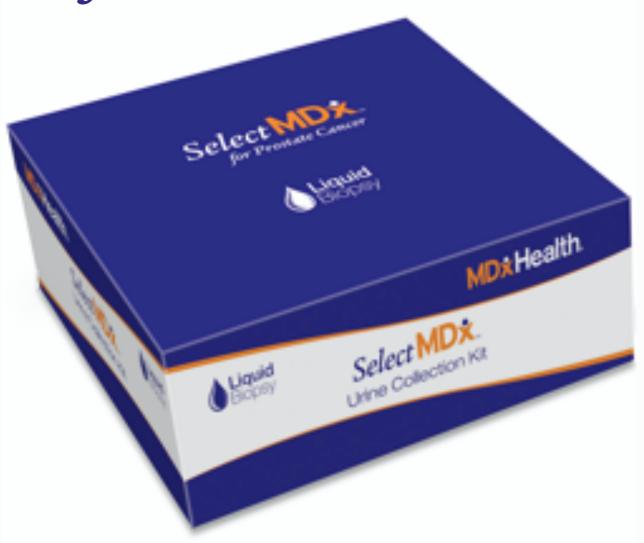
- Avoid unnecessary repeat biopsies
- Uses left over tissue



### Valuable liquid biopsy test for physicians and patients

MDxHealth first liquid biopsy test





Avoid unnecessary biopsies



#### **The Product**

- Proprietary mRNA test
- NPV 98% for high-grade prostate cancer



#### **The Urologist**

Provides actionable information

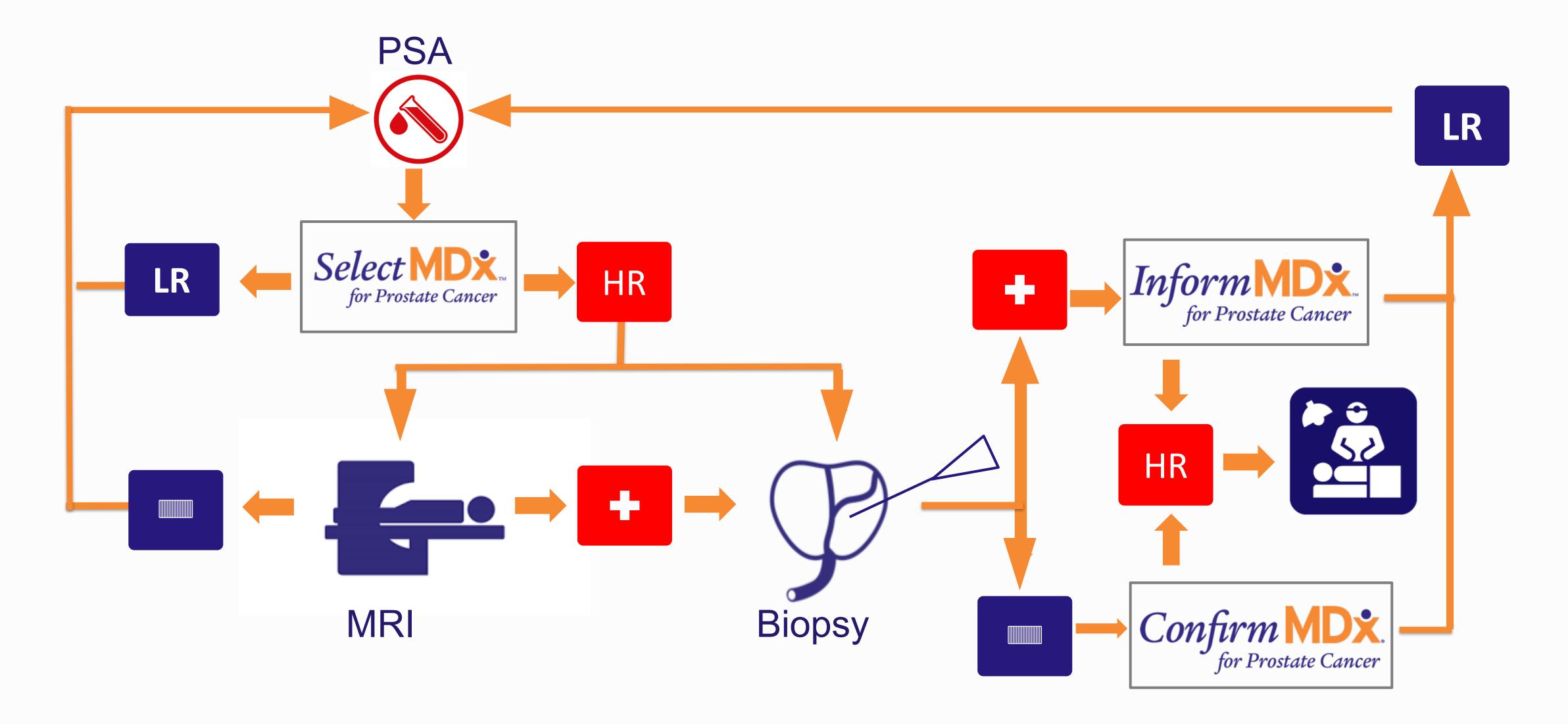


#### **The Patient**

- Avoid unnecessary biopsies
- Non-invasive, only requires a urine sample



### Clinical application of MDxhealth biomarker tests





#### Success of ConfirmMDx & SelectMDx since launch





>65,000

tests completed since launch May 2012





>10,000

tests completed since launch May 2016



## A global billion dollar market for SelectMDx & ConfirmMDx





## Successful global commercial strategy

## Patients

- Forgo unnecessary procedures
- > 75,000 patients tested





## **Q** Visibility

- Strong brand and market validation
- > 60 scientific publications

## Physicians

- Provides actionable information
- ~ 4,000 have ordered tests

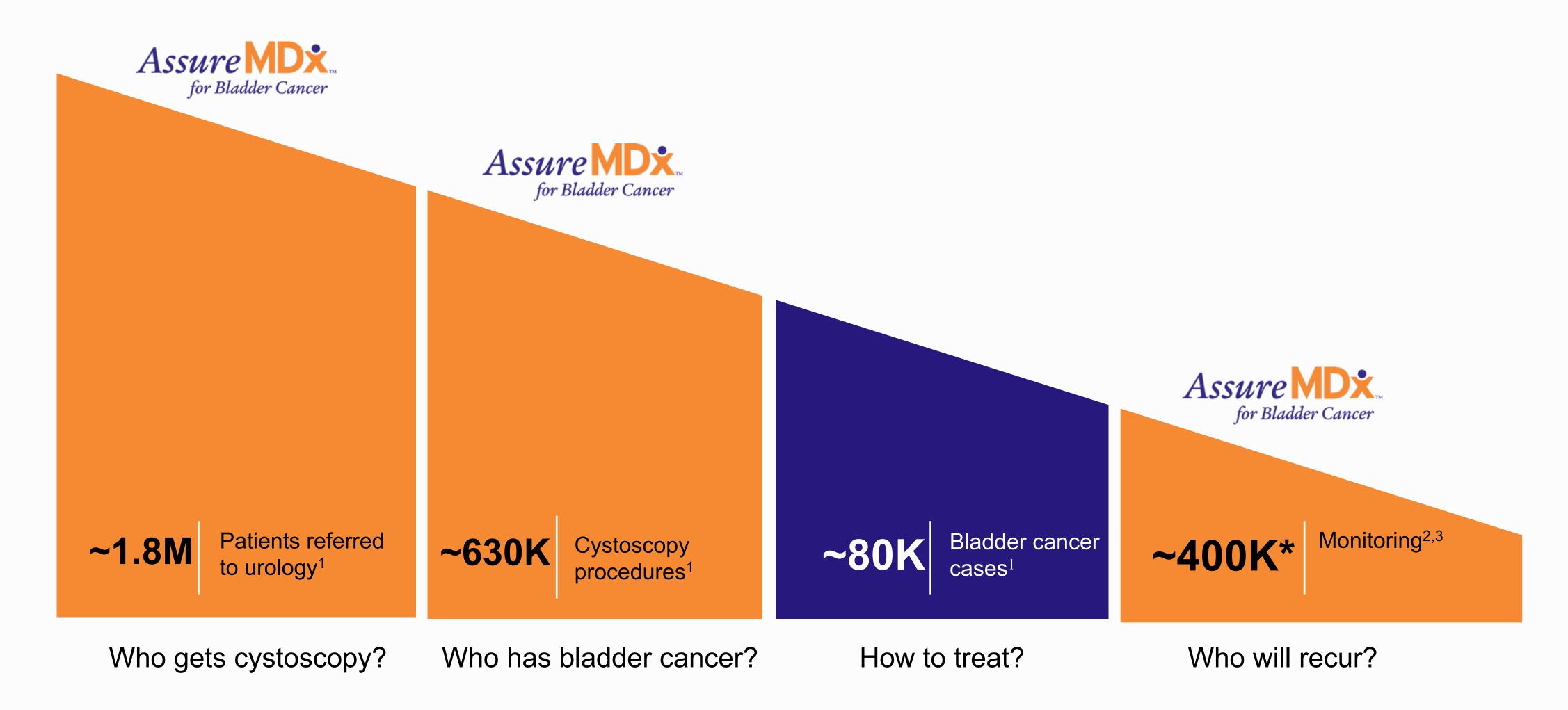
## **Example 2** Credibility

- Covered by CMS, VA, Kaiser
- NCCN guidelines



## MDxHealth bladder cancer diagnosis opportunity

AssureMDx becomes the standard of care in bladder cancer





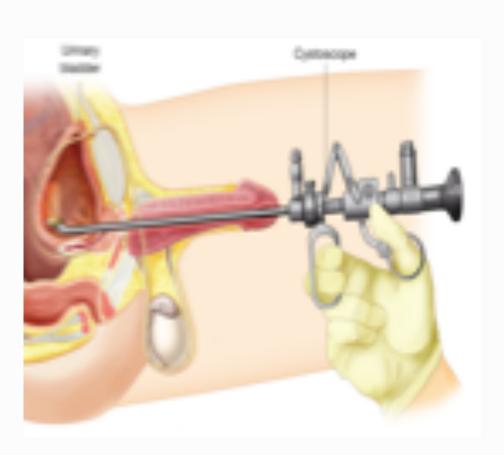
## Bladder cancer diagnosis standard of care

Bladder cancer is the most expensive cancer to treat

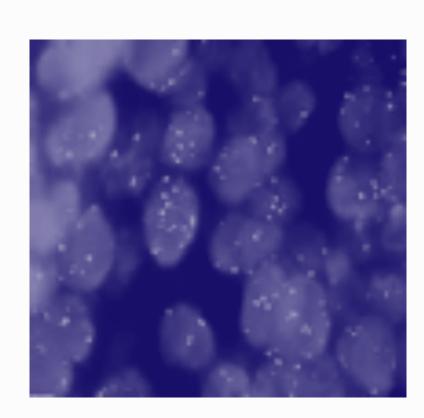
#### Bladder wash/urine sample



Cystoscopy



Cytology





# US bladder cancer market expands our opportunity by \$500M

Million hematuria cases annually

630K cystoscopy procedures

3K missed diagnosis

38K unnecessary cystoscopies

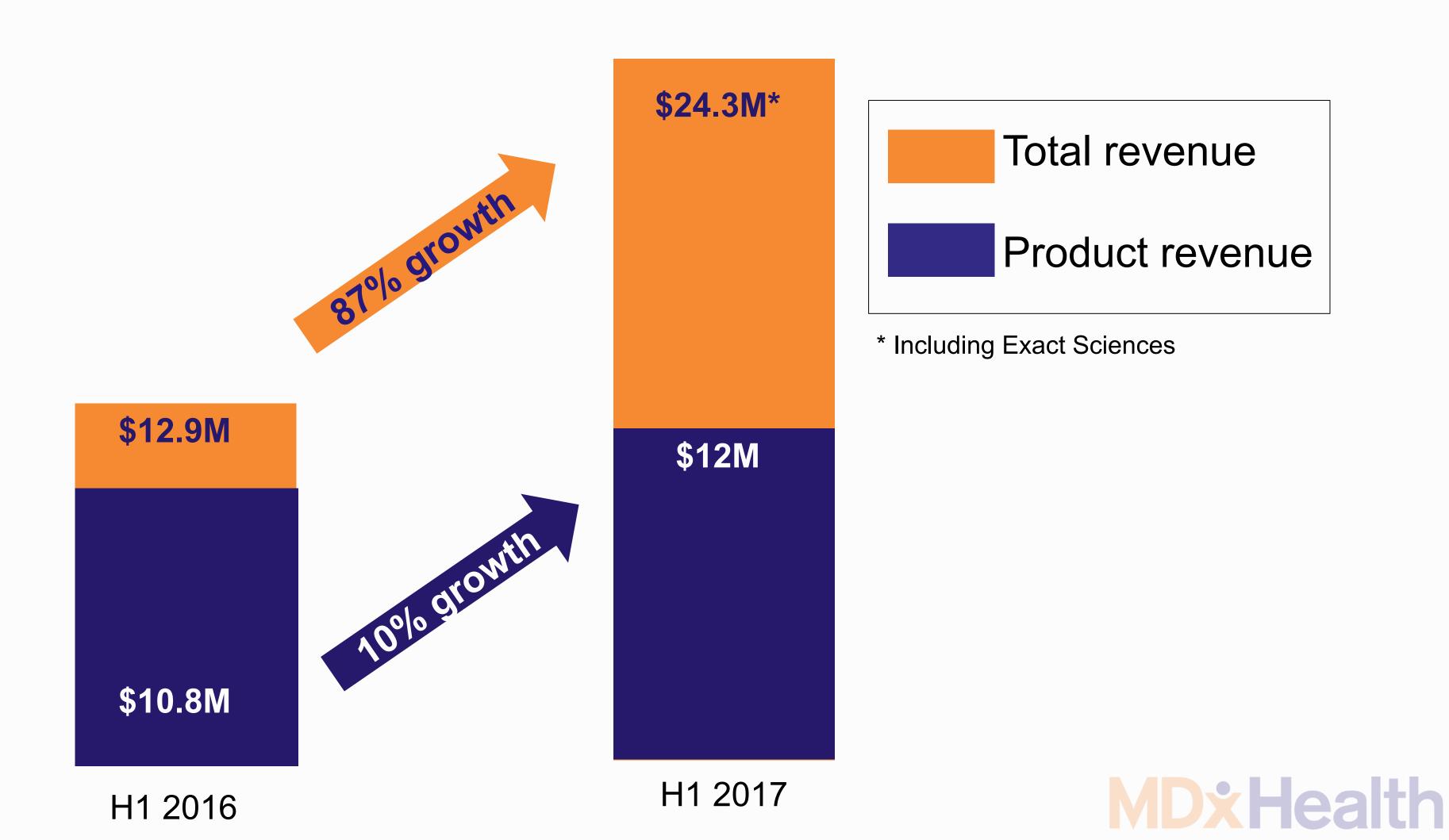




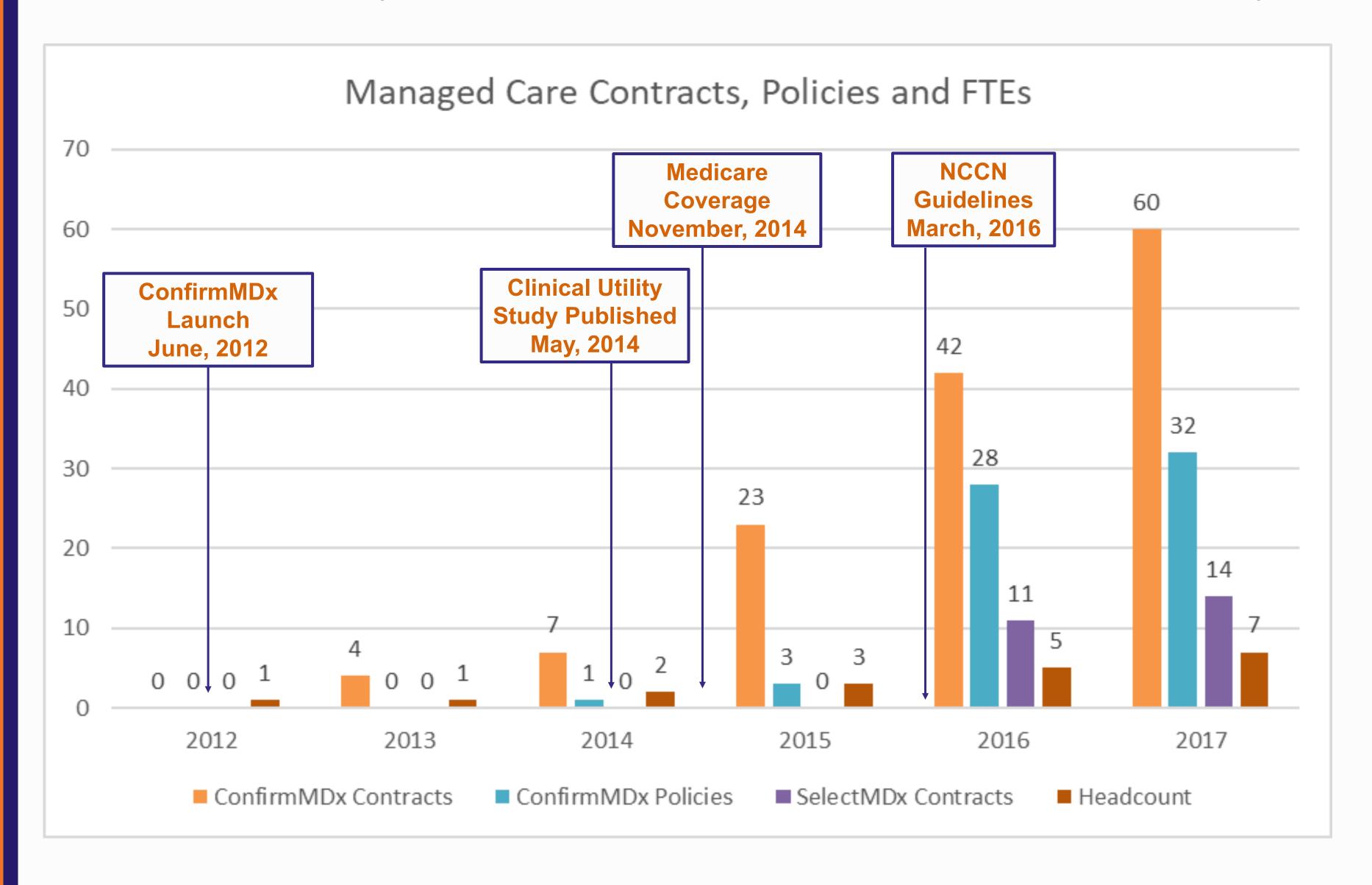


#### Continued revenue growth

Total revenue compared to product revenue growth



#### Payer contract and commercial policy summary

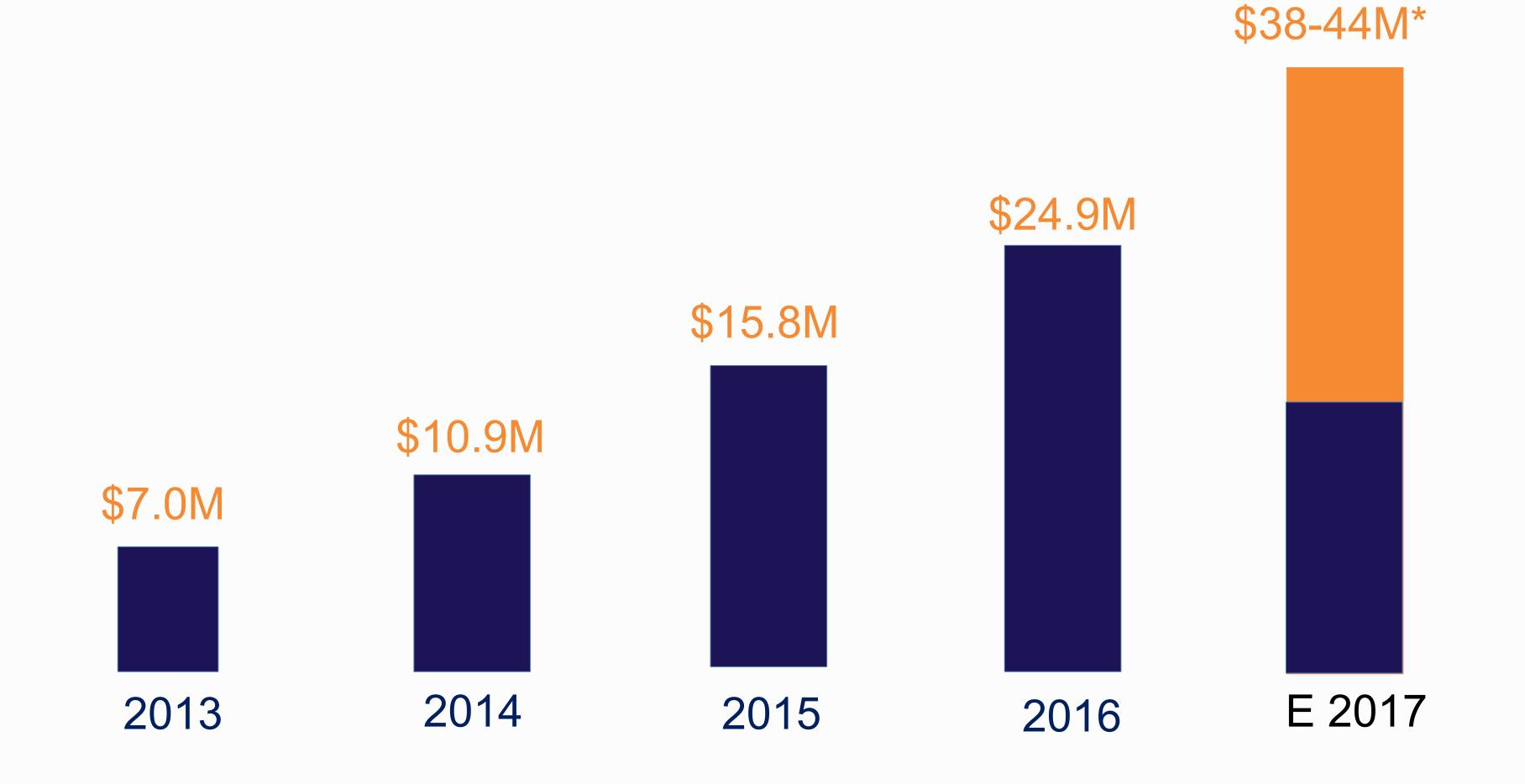


## 2017 YTD accomplishments

- 18 ConfirmMDx contracts closed
- 4 ConfirmMDx commercial policies established
- 3 SelectMDx contracts



## We expect to make guidance—increased reimbursement <sup>23</sup> in H1 historically propels ConfirmMDx growth in H2



**MD**xHealth

## Additional key figures for H1 2017

Key unaudited consolidated figures for the six months ended June 30, 2017 (thousands of US dollars, except per share data):

As of or for the six months ended June 30	2017	2016	Change	Change as a %
Revenue	24,260	12,945	11,315	87.4%
Gross profit	19,261	8,457	10,804	127.8%
Operating expenses	(18,709)	(15,985)	(2,724)	(17.0)%
EBITDA (profit/(loss))	1,433	(6,699)	8,132	
Operating profit/(loss) (EBIT)	552	(7,528)	8,080	
Net income/(loss)	538	(7,618)	8,156	
Earnings per share, basic (\$)	0.01	(0.17)	0.18	

#### 2017 outlook



55-75% growth on product and service income



Continued reduction in operating losses



Improved collectability & reduced working capital requirements



Increased private US payor adoption & favourable reimbursement rates





