OVERALL PERFORMANCE OF THE BD ONCLARITY™ HPV ASSAY IN WOMEN ≥25 YEARS ENROLLED IN THE U.S. REGISTRATIONAL TRIAL

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The BD Onclarity™ HPV Assay is CE-marked in the EU; however, this product is not approved for clinical diagnostic use in the United States and several other global markets. Contact your local sales representative for availability.

BD Onclarity US Study

Disclosures

- Drs. Wright and Stoler served as pathologists for the study and are consultants and speakers for BD Life Sciences
- Other authors are employees of BD Life Sciences
- Study was funded by BD Life Sciences

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Objectives

- In women ≥21 yrs of age with ASC-US

  Evaluate Onclarity as a test to determine the need for referral to colposcopy

  Evaluate genotyping for 16, 18, 45 with Onclarity

- In women ≥30 yrs of age

  Evaluate Onclarity as an adjunctive test to be utilized with cytology (e.g., "cotesting")

  Evaluate genotyping for 16, 18, 45 with Onclarity

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Additional objectives

- Assess the performance of Onclarity as a primary screening test
- Evaluate the clinical utility of broader genotype information provided by Onclarity for the identification of cervical disease and abnormal cytology classification

Onclarity HPV Assay

- 3-well assay with 9 HPV genotype readouts
- Type-specific PCR for HPV E6 or E7 DNA
- Human β-globin control (IC) in each well

G1	G2	G3
• **HPV 16** • **HPV 18** • **HPV 45** • **IC**	• **HPV 33, 58** • **HPV 31** • **HPV 56, 59, 66** • **IC**	• **HPV 51** • **HPV 52** • **HPV 35, 39, 68** • **IC**

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Overall description

- Three year longitudinal study started September 2014 and is expected continue until 2019
- 31 clinical sites in 18 different states
- ***33,858 subjects, >6000 with colpo & CxBx***
- Two specimens: SP (1st) and TP (2nd)
- **SP:** Cytology (manual & masked to HPV) & Onclarity
- **TP:** hc2, sequencing, plus saved for additional studies

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METHODS – Colposcopy examination

- Women with ≥ASC-US or HPV (+) ***(either Onclarity or hc2)*** are referred to colposcopy
- Random subset of cytology and HPV (-) women are referred to colposcopy for VBA
- Colposcopists ***blinded*** to HPV and cytology
- ECC and biopsy of all lesions and acetowhite areas *(random biopsy at SCJ if none present)*
- Endpoint - adjudicated pathology review, ***blinded***

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Demographics of enrolled subjects

Characteristic	Overall
Number	33,400
Mean Age (yrs)	38.6
Race	
White	26,085 (78.1%)
African American	6,306 (18.9%)
Asian	459 (1.4%)
Other	550 (1.6%)
Hispanic or Latino	6,500 (19.5%)

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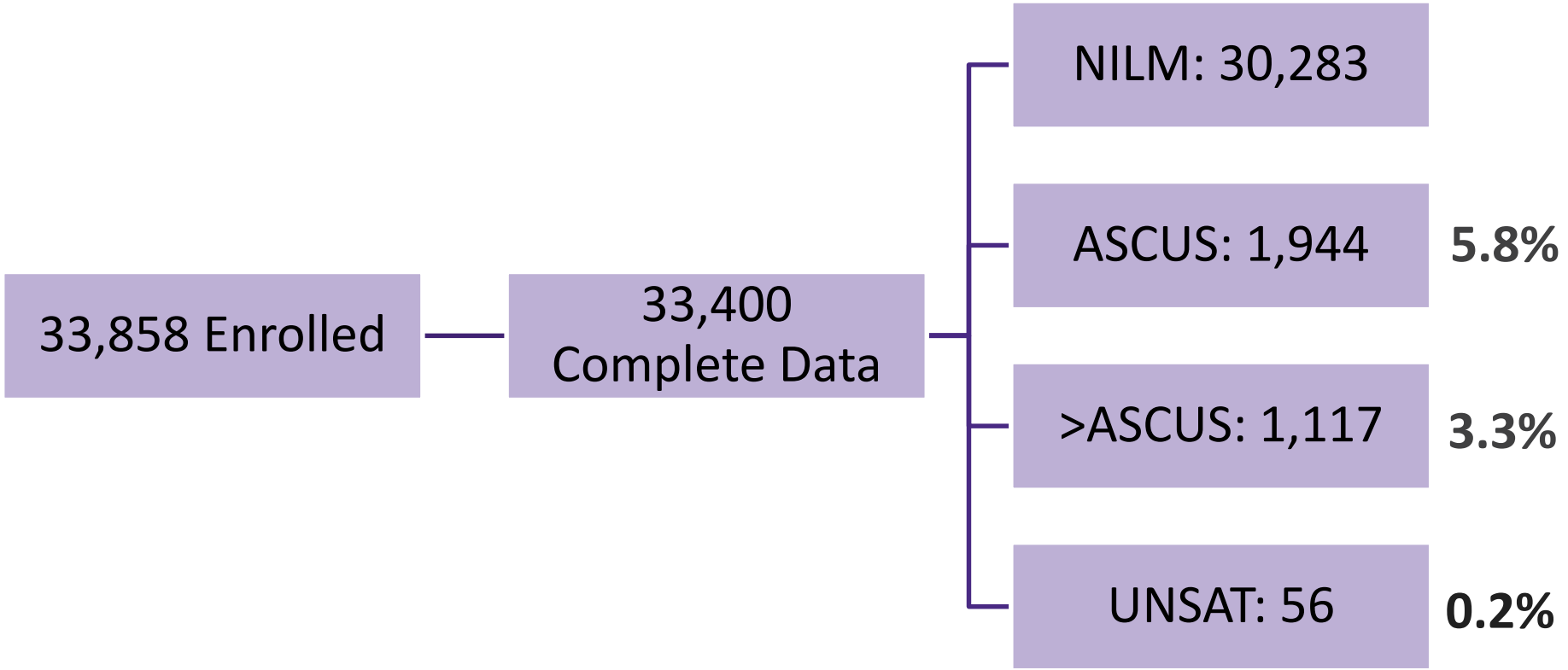
Demographics of enrolled subjects

Characteristic	Overall
Postmenopausal	5,904 (17.7%)
HPV vaccinated	3,042 (9.1%)
Abnormal Pap in last 5 yrs	4,749 (14.2%)
Colposcopy in last 5 yrs	2,990 (9.0%)

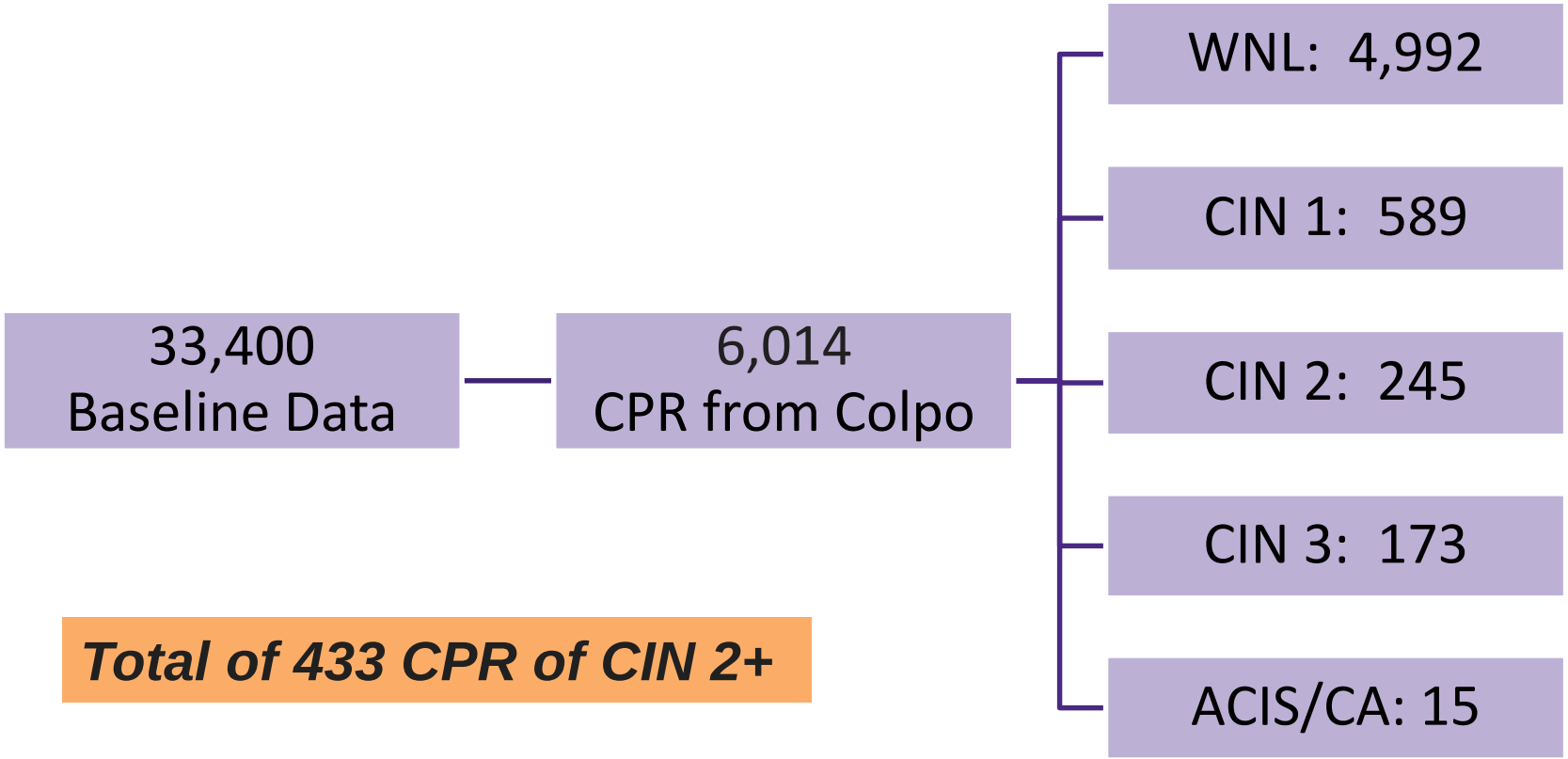
Subject Enrollment

Results of baseline cytology



Subject Enrollment

*Consensus pathology results **(CPR)** from colposcopy*



Total of 433 CPR of CIN 2+

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*Performance using a **CIN 3+** endpoint*

Measure	Crude Estimates		VBA Estimates	
	Onclarity	Pap	Onclarity	Pap
Sensitivity	93%	59%	78%	50%
Specificity	48%	64%	89%	92%
PPV	6%	5%	6%	5%
NPV	99%	98%	99%	99.5%

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*Performance using a **CIN 3+** endpoint*

Measure	Crude Estimates		VBA Estimates	
	Onclarity	hc2	Onclarity	hc2
Sensitivity	93%	90%	78%	76%
Specificity	48%	49%	89%	89%
PPV	6%	5%	6%	5%
NPV	99%	98%	99%	99%

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*Performance using a **CIN 3+** endpoint*

Measure	Crude Estimates		VBA Estimates	
	Onclarity	cobas[1]	Onclarity	cobas[1]
Sensitivity	93%	92%	78%	75%
Specificity	48%	57%	89%	90%
PPV	6%	7%	6%	7%
NPV	99%	99.5%	99%	99%

[1]Castle et al. Lancet Oncology 2011

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Conclusions

- Large registration trial with considerable power to clinically validate the Onclarity HPV test
- The sensitivity, specificity, PPV and NPV using both a CIN 2+ and a CIN 3+ endpoint of Onclarity run with SurePath in women 25+ years is comparable to that of hc2 run with ThinPrep
- Sensitivity of Onclarity is considerably greater than that of cytology