

**IDENTIFY**



# IDENTIFY: The **I**nvestigation and **DE**tECTION of Urological **N**eoplasia in **Pa**Tients **re**Ferred with suspected urinary **Y** tract cancer – A Multicenter study

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***The IDENTIFY Study Group***

# Potential Conflict of Interest Disclosure

- No conflicts of interest to disclose

# Introduction

- Hematuria

- BURST Urology

**IDENIFY**

Refer people using a suspected cancer pathway referral (for an appointment within 2 weeks) for bladder cancer if they are:

- aged 45 and over and have:
  - unexplained visible haematuria without urinary tract infection or
  - visible haematuria that persists or recurs after successful treatment of urinary tract infection, or
- are aged 60 and over and have unexplained non-visible haematuria and either dysuria or a raised white cell count on a blood test. [new 2015]

Consider non-urgent referral for bladder cancer in people aged 60 and over with recurrent or persistent unexplained urinary tract infection. [new 2015]

Multi-centre international collaborative project assessing **outcomes and diagnostic pathways** for patients referred with **suspected urinary tract malignancy**

# Project Outline



## **Phase 1:** Development/Clinical Question

How can we improve the detection of urologic malignancies in patients investigated for hematuria?



## **Phase 2:** Pilot

825 patients, 7 hospitals - confirmed feasibility and finalized database development



## **Phase 3:** Recruitment

National leads, ethics, establish local REDCap databases



## **Phase 4:** Data Acquisition & Cleaning

**Phase 5:** *Statistical Analysis/Result Synthesis/Publications*

**Phase 6:** *Practice Change*

# REDCap Database



## Inclusion Criteria

- Patient undergoing cystoscopy for the purpose of exclusion of urological malignancy

## Exclusion Criteria

- Previous urological malignancy
- Cystoscopy for a reason unrelated to ruling out urological malignancy

- Detailed demographics
- Presentation and past history
- Diagnostic Cystoscopy
- Investigations (primary, staging, follow up)
- Primary Outcome
- Follow-up Outcomes
- Repeat Imaging
- Final Outcome

## Regarding this episode and associated features:

LUTS

Are there any lower urinary tract symptoms (LUTS)?  
(Select only one - select mixed if both storage and voiding LUTS are present)

- None
  - Voiding/ Obstructive LUTS
  - Storage/ Irritative LUTS
  - Mixed LUTS
- ((Select only one option - select mixed if both storage and voiding LUTS are present))

LUTS definition

### Voiding/ Obstructive LUTS (e.g. BPH):

- Hesitancy: A longer than usual wait for urine stream to begin
- Poor stream: A weak stream of urine
- Straining to urinate
- Dribbling after urination
- Overflow incontinence
- Incomplete emptying

### Storage/ Irritative LUTS (e.g. OAB):

- Urgency
- Frequency
- Nocturia (two or more during the night)
- Urge incontinence

Associated symptoms

Does the patient have any urinary incontinence, dysuria/suprapubic pain or flank pain?  
(Select all that apply)

- Incontinence
  - Dysuria / Suprapubic pain
  - Flank pain
  - None
- ((Select all that apply). Incontinence is the involuntary loss of urine. Dysuria is pain or discomfort associated with passing urine.)

# Canadian Data Collection



- Sep 2017: UofA involved as Canadian Coordinators

## Top 5 Recruiting Centers:

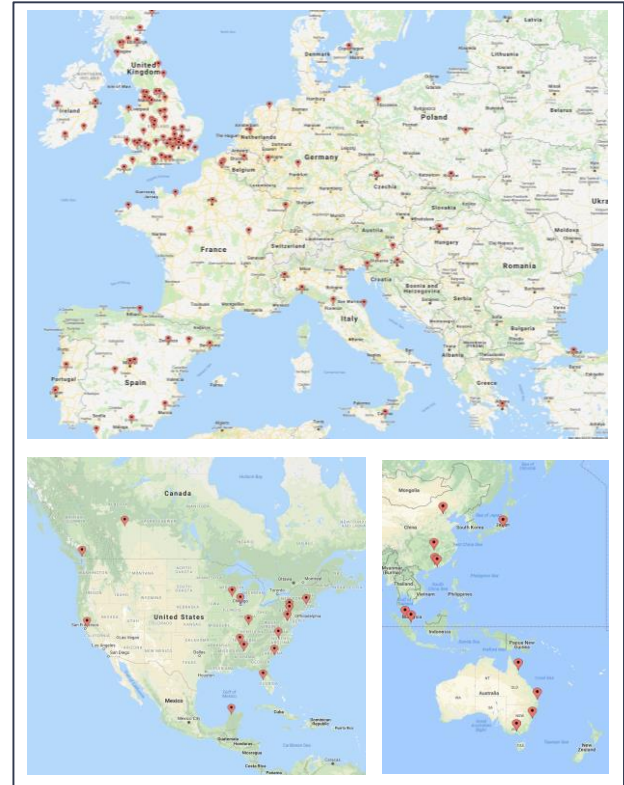
- i. **Vancouver General Hospital - Canada**
- ii. Cattinara – Italy
- iii. SanGiovanni Battista Hospital – Italy
- iv. **University of Alberta – Canada**
- v. Royal Derby Hospital - UK

## Canadian Contribution:

Minimum requirement: 100 patients

Achieved: **1021** patients

~9.5% of total study enrollment



# Preliminary Data: Patient Enrollment



## Initial Raw Database

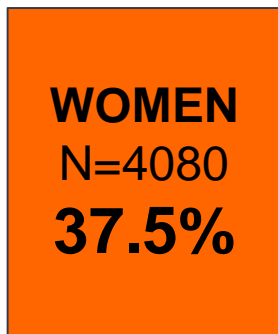
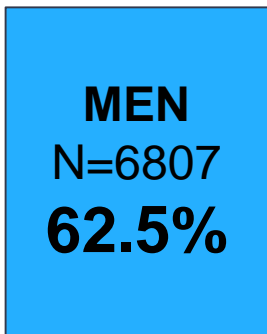
- 11,059 patients
- 128 sites
- 30 countries



## After Data Cleaning

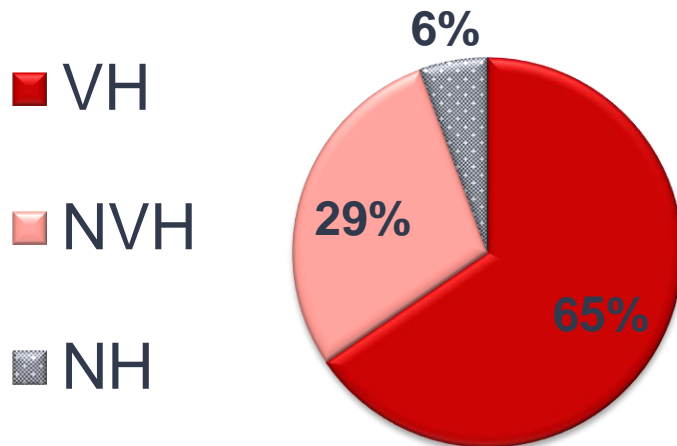
- **10,952 patients**
  - 110 sites
  - 27 countries

## Preliminary Data: Characteristics



**Median age = 66**

## Reason For Referral



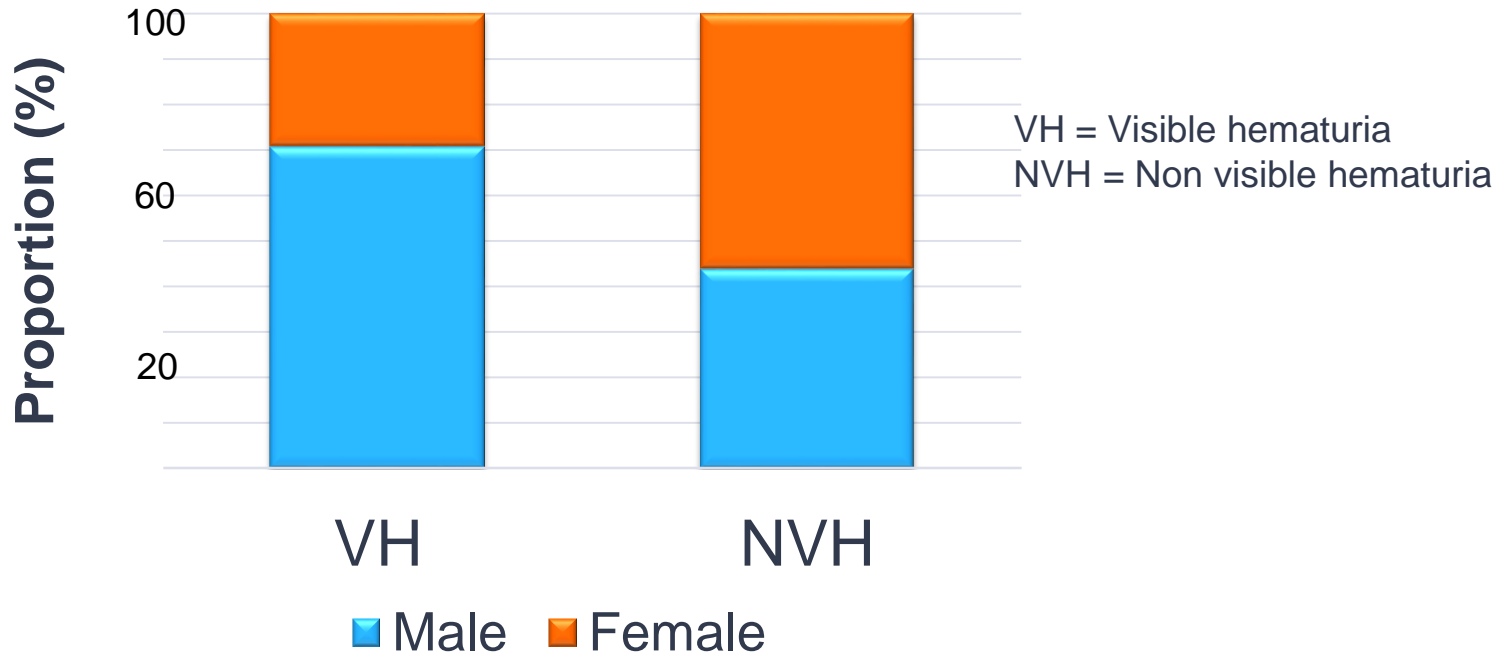
VH = Visible hematuria  
NVH = Non visible hematuria  
NH = No hematuria



# Preliminary Data: Characteristics



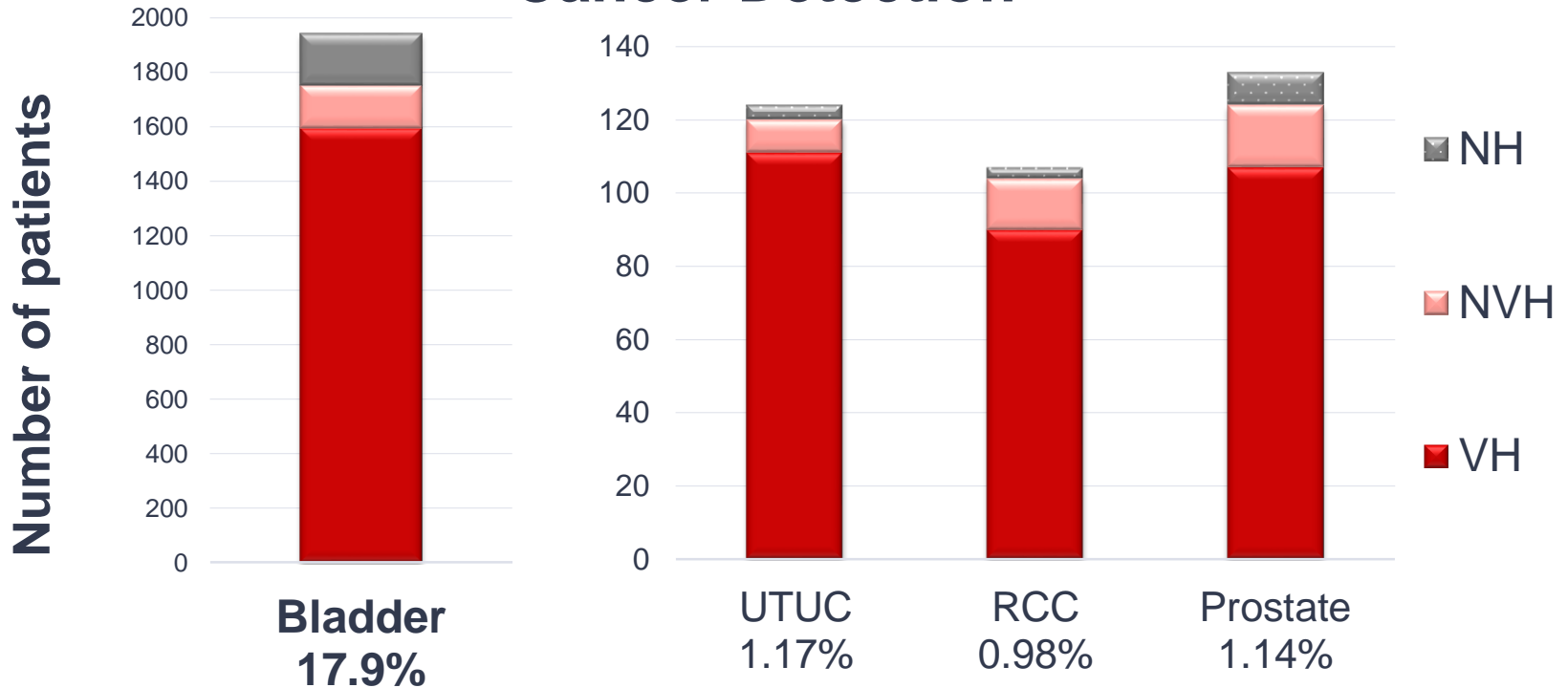
## Hematuria By Gender



# Preliminary Data: Cancer Detection



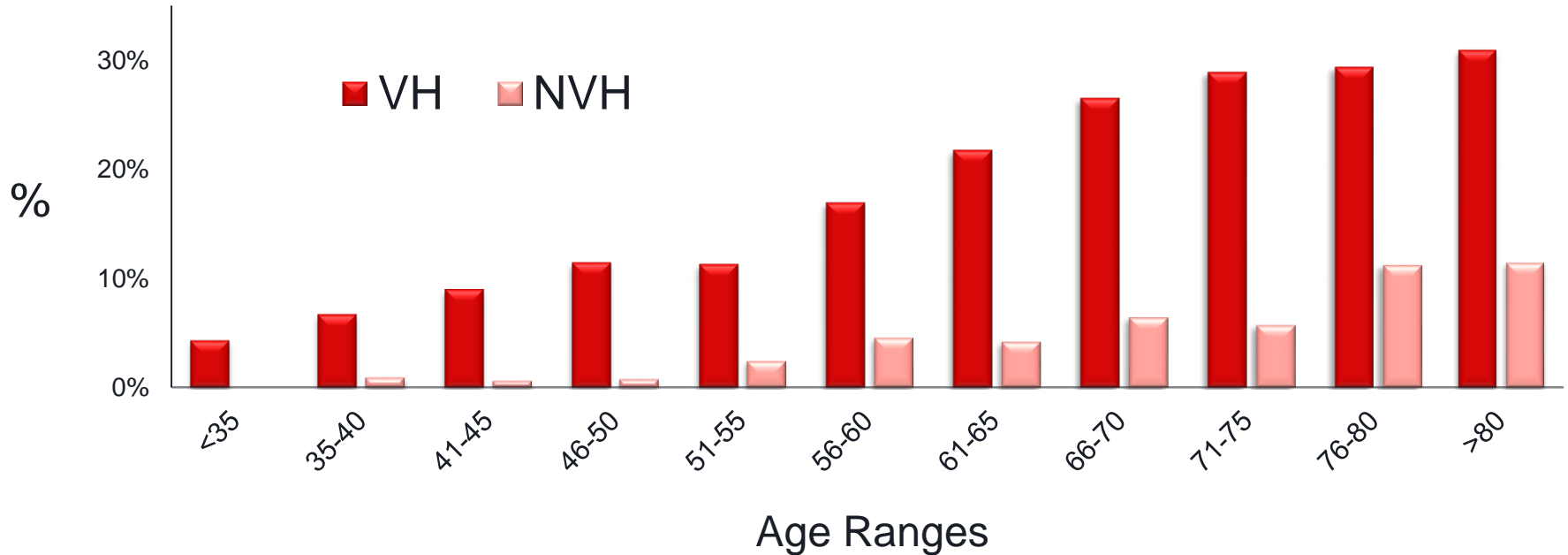
## Cancer Detection



# Preliminary Data: Cancer Detection



## Detection of Bladder Cancer in VH and NVH Patients by Age



# Preliminary Data: Imaging Modalities



<b>Urologic Malignancy</b>	<b>Imaging modality</b>	<b>Sensitivity (%) (95% CI)</b>	<b>Specificity (%) (95% CI)</b>	<b>Positive Predictive Value (%) (95% CI)</b>	<b>Negative Predictive Value (%) (95% CI)</b>
BC	US	77.8 (74.4-81.0)	93.5 (92.7-94.3)	67.8 (64.9-70.5)	96.0 (95.5-96.6)
	Contrast CT	80.5 (77.3-83.4)	92.3 (91.3-93.3)	71.5 (68.7-74.1)	95.2 (94.4-95.9)
UTUC	US	42.5 (27.0-59.1)	97.7 (97.3-98.1)	12.7 (12.4-27.7)	99.5 (99.4-99.7)
	CT Urogram	95.7 (88.0-99.1)	94.4 (93.5-95.2)	26.8 (24.0-29.8)	99.9 (99.7-99.97)

# Conclusions

- ✓ **IDENTIFY is the largest, prospective, international study of patients referred to secondary care with hematuria**
- ✓ Provides **contemporary cancer detection rates in a global population** alongside extensive predictive data and diagnostic test performance for multiple urologic malignancies
- ✓ Ongoing analysis aims to improve shared decision-making and **optimize cancer detection while minimizing investigation burden**

**Questions?**