Clinical Trial Efficiency – Patient Identification Model for Protected PCI

Dan Housman, Chief Technology Officer, Graticule (dhousman@graticule.life)

Dawn Bardot, PhD GM Global Service and Cloud Product, Abiomed

INTRODUCTIONS

Dawn Bardot, PhD
GM Global Service and Cloud Product, Abiomed

- Background in medical devices including ultrasound, noninvasive FFR and cardiology solutions
- Former Innovation Director at *Medtronic* and VP of Innovation at *Medical Device Innovation Consortium*, a public/private partnership between the FDA, patient groups and medical device industry.

About Abiomed

- Leading provider of medical technology that provides circulatory support and oxygenation, acquired by J&J (2022)
- Founded 1981 with the purpose to develop world's first artificial heart
- 18+ year strategic focus on heart recovery therapies (blood flow, oxygenation for respiratory failure patients)

Dan Housman
Chief Technology Officer, Graticule

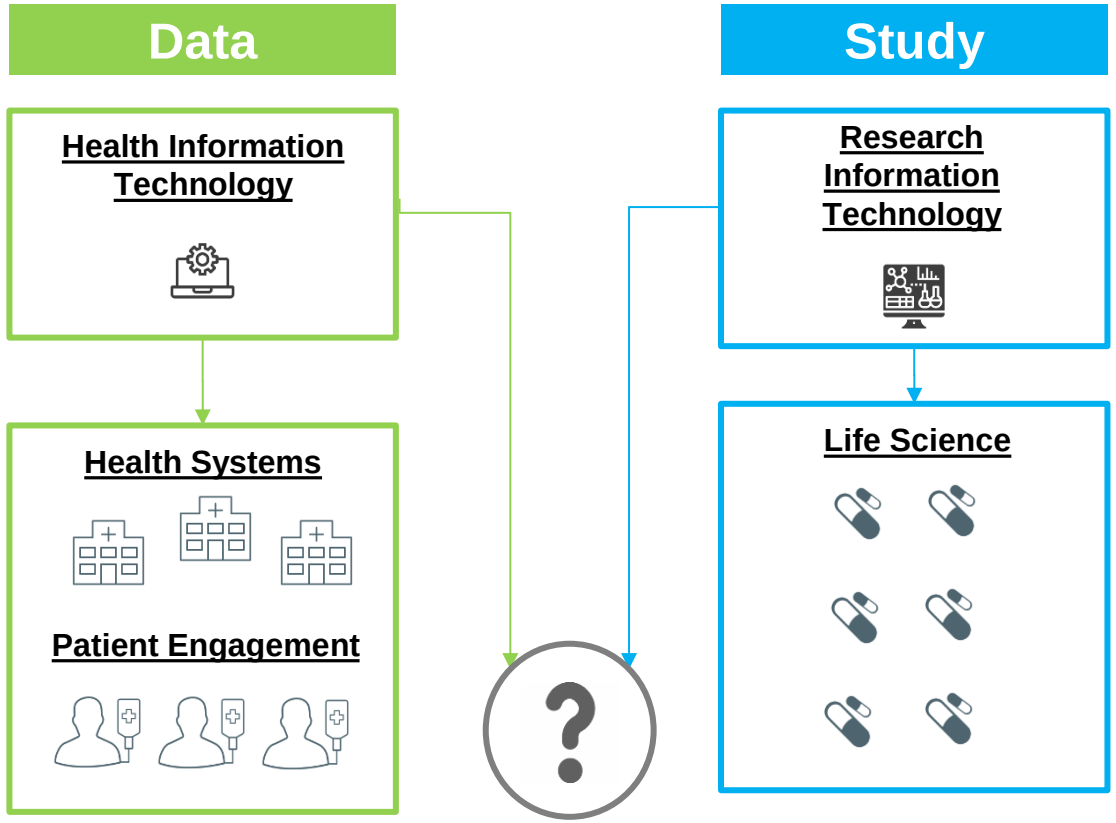
- Background in real-world data, interoperability, and clinical analytics
- Co founder of *Graticule* and *Recombinant Data*
- Former CTO of healthcare analytics for *Deloitte*

About Graticule

- On-demand real-world data and advisory services provider
- Founded in 2018 by Dan and CEO, Dan Poscover
- Innovation focus on data resource optimization for neurology, cardiology, oncology and rare disease clinical research

CLINICAL TRIALS ARE INEFFICIENT BECAUSE IT SYSTEMS ARE NOT COMPATIBLE

Current State

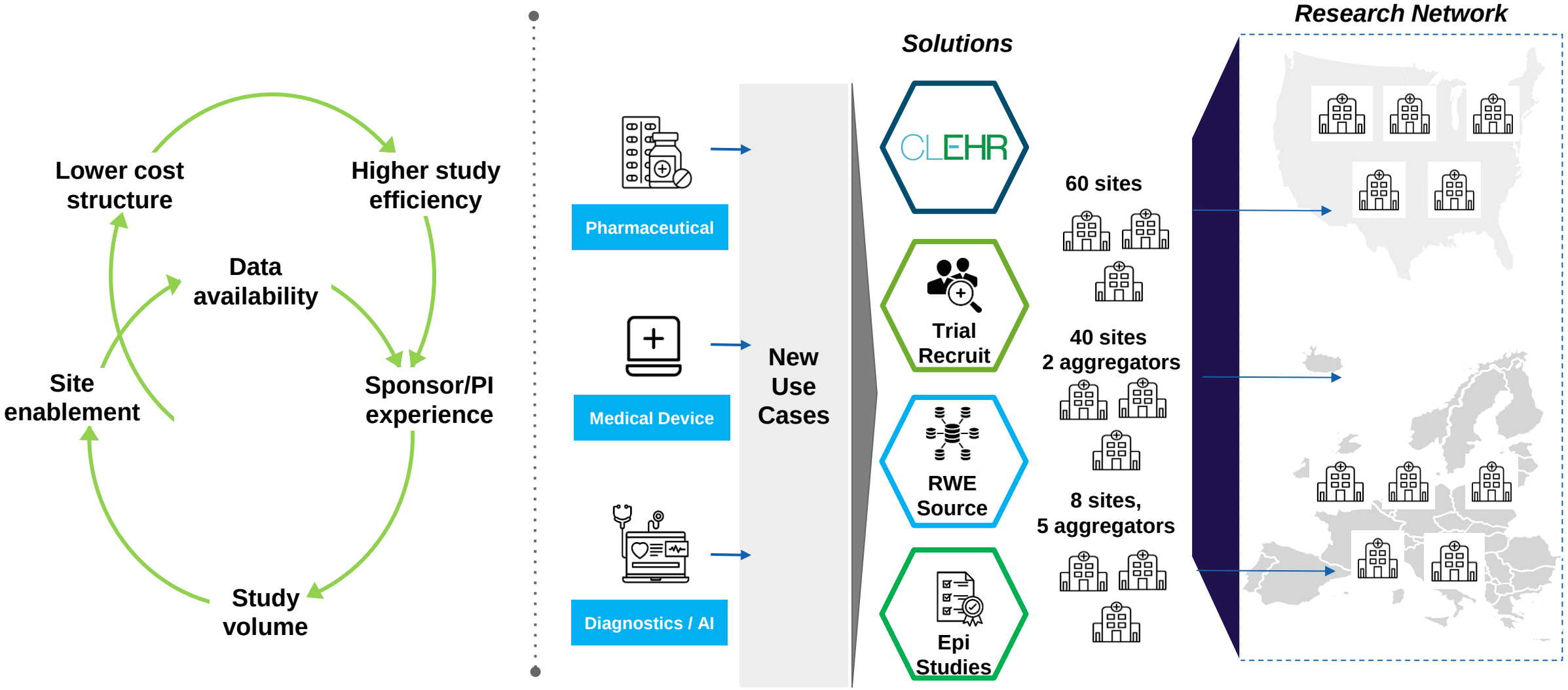


Datanemia

Limited Results	
	Data doesn't move without deidentification
	Recruitment can't be optimized centrally
	Lack of access to advanced data (notes, images, genetics)
	Inefficient copy-pasting or manual recruitment methods in clinical research studies
	Validation procedures must resolve quality issues

RESEARCH NETWORK EFFECT FOR EHR INTEGRATION

Increased use through studies generate superior capabilities from network growth and maturity



LOST PATIENTS MEANS LOST OPPORTUNITY FOR LIFE SAVING THERAPY

Current practice: patients who may benefit from PCI procedure get overlooked

Why patients may get left behind

- **Missed Referrals**: Patients eligible for ischemic workup are sometimes missed by clinicians
- **Low Referrals**: Limited relationships between primary care/cardiologists or interventional cardiologists are often influenced by geographical factors, leading to low referrals
- **Variability in Approach**: Clinicians differ in their strategies for managing high-risk patients
- **Missed Opportunities**: Limited chances to identify eligible patients during scheduled visits, suggesting a need for proactive outreach

ADVANCED SCREENER IDENTIFIES PATIENTS OVERLOOKED IN CURRENT PRACTICE

Why a clinical decision support tool that provides prioritized lists of patients based on screener scores?

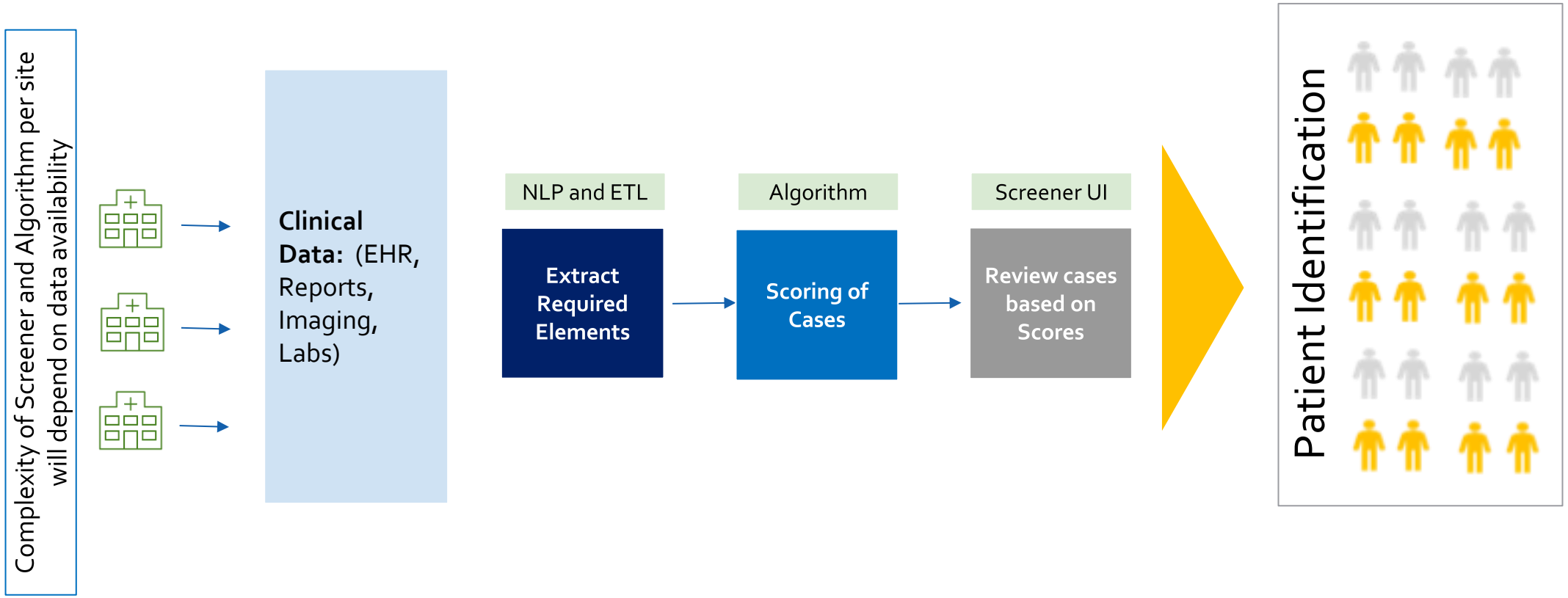
Improved patient access to a safer procedure for high-risk PCI patients

Better clinical outcomes through early identification

Active recruitment into clinical trials for patients who could benefit from a procedure that may be better than standard of care

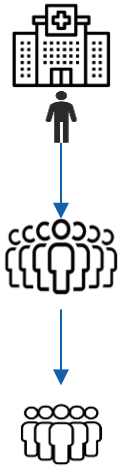
COMPLEMENT THE DECISION MAKING IN CARDIOLOGY PATIENT CARE

The screener assists clinical staff to determine if each case qualifies for a protected PCI by extracting clinical data from the EHR



IDENTIFY CASES OF INTEREST FOR PATIENTS WHO MAY BENEFIT FROM PCI

The screener identifies patients of interest and provides relevant clinical details to the clinical staff for review

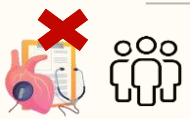


Health System
Total Patient Population ~2M

Preliminary Screener Cohort
Patients with CAD or undiagnosed CAD or having LVEF<=45% ~11K

Final Screener Cohort
Excludes patients who have undergone revascularization procedures ~7K

~2K



Sub Cohort 1
No Ischemic Evaluation & Low LVEF

Allows for identification of patients who have not been evaluated and can be targeted for a ischemic evaluation workup or follow-up with clinician for candidacy

~1K

Sub Cohort 2
Obstructive CAD & Unrevascularized & Low LVEF

Allows for identification of immediate candidates for further assessment and intervention

Cases of Interest

Other Sub Cohorts
Deprioritized for Review

- Low LVEF & Obstructive CAD & Revascularized
- Low LVEF & Not Revascularized & Obstructive CAD unknown
- Low LVEF & Non-obstructive CAD
- LVEF >45%

CLINICIAN'S VIEW OF EXTRACTED, RELEVANT CLINICAL FEATURES

Patient Details | Final Score & Sub Cohort | Clinical information extracted from radiology reports | Summary for clinicians | Workflow to track shortlisted cases…

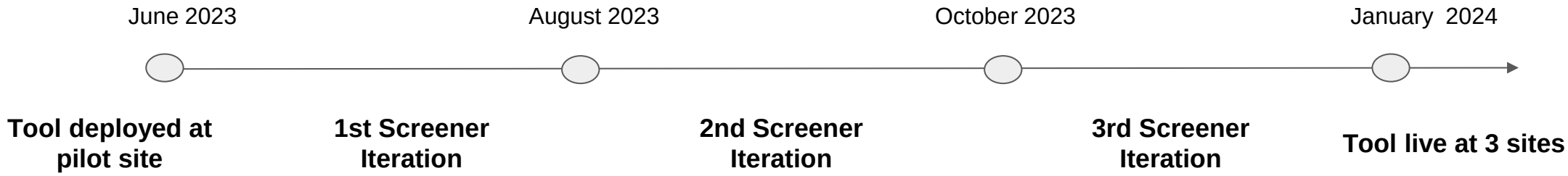
Patient MRN	De-identified Patient Id	First Name	Last Name	Zip code	City	Final Score	Sub-cohort for review	Obstructive CAD	Obstructive CAD Score	Latest date of obstructive CAD /non-obstructive CAD	Feature extracted	Radiology report snippets	Screener Summary	LVEF History	Chronology of Health Events	Date of 1st Review
AAGZZDHYYMRAQNPBJMRQ2N1944	dad4535cf12c1d2ca497dabd41c09b384087e2aa881a8c236bf014e80d369832	Merill	Clace	38116	Memphis	127	Low LVEF and obstructive CAD and unrevascularized	Yes, left main disease	20	04/06/2020	Obstructive CAD: Extracted from ANGIOGRAM, CORONARY ARTERY on 04/06/2020	ANGIOGRAM, CORONARY ARTERY on 04/06/2020: m lesion was 50% stenosed. · the dist lad lesion was 50% stenosed. patent stent in the proximal lad. · the estimated blood loss was none. · there was left main disease. after informed consent was obtained, patient was brought to the cardiac catheterization laboratory in a fasting state where patient was prepped and draped in the usual sterile fashion.	Obstructive CAD Score: Obstructive CAD (Score: 20) Age = 47 (Score: 1) Gender = F Family History of Cardiac Disease = Yes Latest LVEF = 27% (Score: 7) Confirmed CAD of native vessel = Yes (Score: 10) Unrevascularized CAD = Yes (Score: 10) CTO = Yes (Score: 5) Major Cardiac Comorbidities = Combined Heart Failure, Peripheral Vascular Disease, Cardiomyopathy-Others/ Unspecified,	07/28/2020: Latest LVEF-27% (From Others) 06/23/2019: Earliest LVEF- 22% (From Labs)	05/20/2022: Latest record of imaging modality- [TTE] 12/24/2021: Latest record of cardiac device 10/05/2021: Latest record of heart failure medication- Entresto 06/09/2021: Latest record of antiarrhythmic drugs 02/22/2021: Latest record of antiplatelet drugs 12/27/2020: Latest record of CTO 12/03/2020: Latest record of antianginal drugs 10/29/2020: Latest record of confirmed CAD of native vessel 08/16/2020: Earliest record of confirmed CAD of native vessel 07/28/2020: Latest record of LVEF(27%) 04/06/2020: Latest record of diagnostic cath/ coronary angiogram 04/07/2019: Latest record of SGLT2	Open - New patient

Extracted features list

- Low LVEF
- CAD Diagnosis
- Conditions/ Medication indicating undiagnosed CAD
- Obstructive CAD or Multivessel CAD extracted from Cath Reports
- Symptoms extracted from Clinical Notes
- Flag for P-IV exclusion conditions

ITERATIVE REFINEMENT APPROACH

The screener tool is being refined over time through feedback from pilot sites



Additional features added to address clinician feedback

1. Provide additional information related to ***Obstructive CAD*** to allow identification of potential cases
2. Flag cases that have records of *conditions that are considered as* ***exclusion criteria in the P-IV study*** to filter out cases that can be deprioritized for review
3. Present information related to ***Viability of myocardium*** to assess cases eligible for procedure based on the viability of myocardium
4. Provide additional information regarding ***Symptomology*** i.e patient symptoms to allow the reviewers in assessing the suitability of a case for protected PCI

LIVE AND RUNNING: DEPLOYMENT AT HEALTH SYSTEMS TO DATE

The tool is being made available to Protect-IV sites for recruitment of eligible patients

	Louisiana-based, 760+ bed provider	*NJ-based, 450+ bed provider*	*Alabama-based, 1,200+ bed provider*	*Florida-based, 1,100+ bed provider*
				
	Site 1	Site 2	Site 3	Site 4
Initial Results	**~ 30% patients** determined by the screener to have **obstructive CAD** identified as **potential** candidates **for HR-PCI**	**1 fit for P4 and 1 fit for HR-PCI** per 22 top ranked cases	**Screener deployed with review in process**	**Screener deployment in process**

Q&A

Dan Housman
(dhousman@graticule.life)