

Biomarkers and clinical parameters associated with Gleason score upgrading

“Upgrading Reference Set”

Current Status

June 30, 2020

Upgrading Reference Set

Leadership

- PIs: Ian Thompson , Robin Leach, Martin Sanda, Paul Boutros
- Data Coordination: Fred Hutchinson Cancer Res CTR
- Pathology: Dean Troyer, EVMS
- Biostatistics: Yingye Zheng, Fred Hutchinson Cancer Research Center

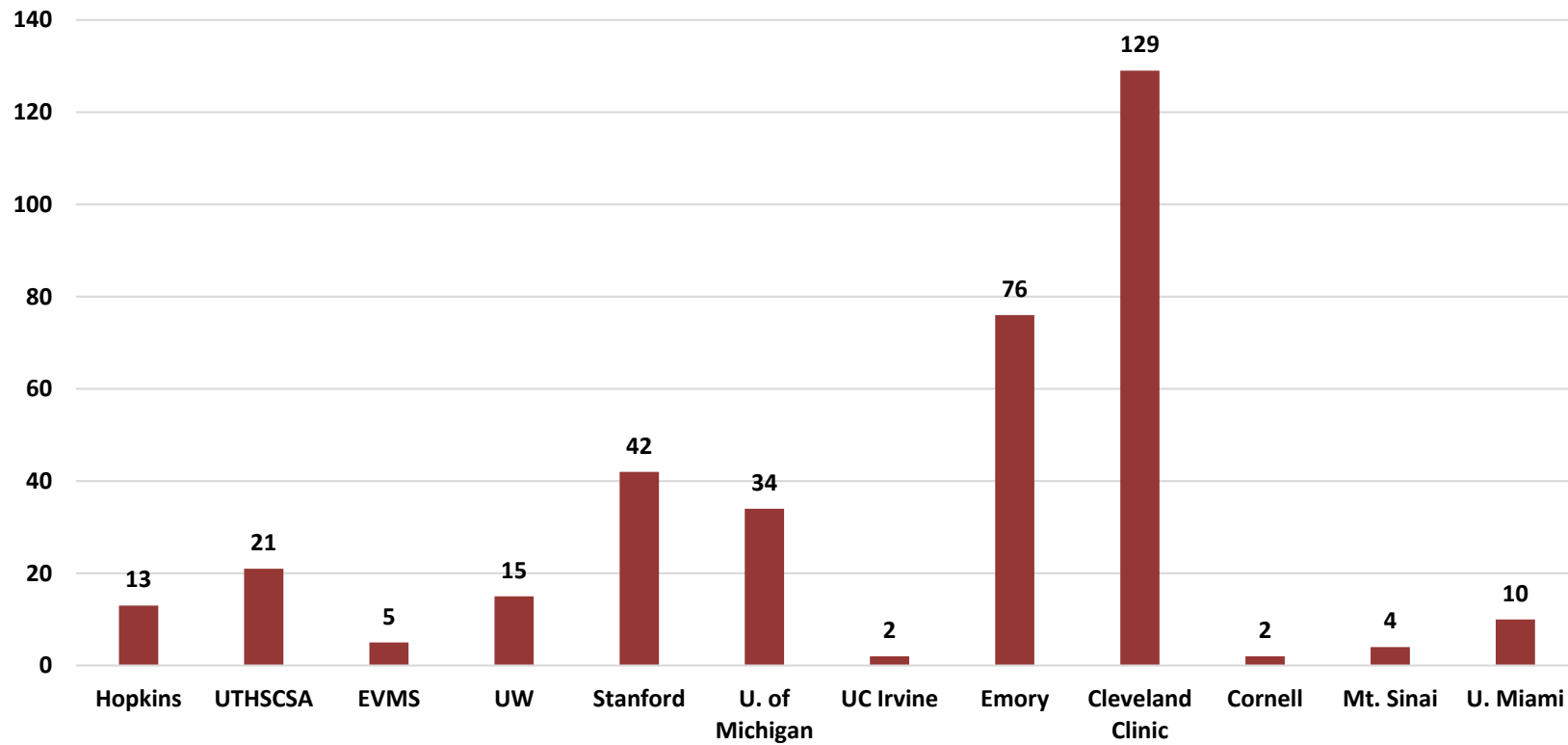
Purpose

A multi-institutional study to identify molecular biomarkers and clinical measures that will predict presence of Gleason 7 or higher cancer (as evidence in the radical prostatectomy specimen) among patients with a biopsy diagnosis of Gleason score ≤ 6 prostate cancer.

Phase III Funded as of September 2019

- Final phase of project obtained Core funding as of September 2019
 - Subcontract received at UT Health in December 2019
 - Subcontracts from UT to clinical and pathology distributed in January 2019
 - Reimbursement covering up to date expenses submitted in May 2020
 - Recruitment and central review inhibited by COVID-19
 - Requesting carryover funds to complete recruitment
- Sequencing of constitutional DNA second aim of Phase III
 - To be conducted at UCLA starting in April 2020
 - Will be used to evaluate PRACTICAL Polygenetic Risk Score
 - MTA near final stages to obtain samples from NCI biorepository

Confirmed Round 1 Enrollment



Total Enrollment: 354

Status Report from June 23, 2020

Pending Round 1	Ineligible Round 1	Confirmed Round 1	Biopsy Sent to Review	Ineligible Round 2	Confirmed Round 2 With Post DRE Urine	Confirmed Round 2 without Post-DRE Urine
6	55	354*	223+	52	197#	70

*Increase of 60 confirmed round 1 since last presentation in 2019

+ All shipping to central review stopped because of COVID-19 in March 2020

#Final goal 240 with 200 “complete sets” to be used for sequencing phase

Distribution Plan

Four Phase Plan

1. Initial Request
2. Full submission proposal with
 - a. Introduction
 - b. Aims
 - c. Preliminary data
3. Assessment of request by Upgrading Reference Set committee
4. MTA request and sample distribution

Upgrading Reference Set Committee

- Dr. Michael Liss (UT Health SA)
- Dr. Karen Rodland (PNNL)
- Dr. Paul Boutros (UCLA/Ontario Inst.)
- Dr. Yingye Zheng (DMCC/Fred Hutch)
- Dr. Robin Leach (UT Health SA)

- Exofficio: Jacob Kagan (NCI)

Discussion Points

- Currently have 267 completers that could be used for serum or plasma markers
- Pathology
 - EVMS is preparing core grant to gather pathology specimens
 - PI will be O. John Semmes and Dean Troyer will serve as pathologist
 - Sites are still holding tissue after the central review
 - First aim of core proposal will focus on gathering specimens
 - Second aim focused on performing multi-probe assessment of specimens