

UC Wide Participant Recruitment

Vanessa Jacoby, MD, MAS

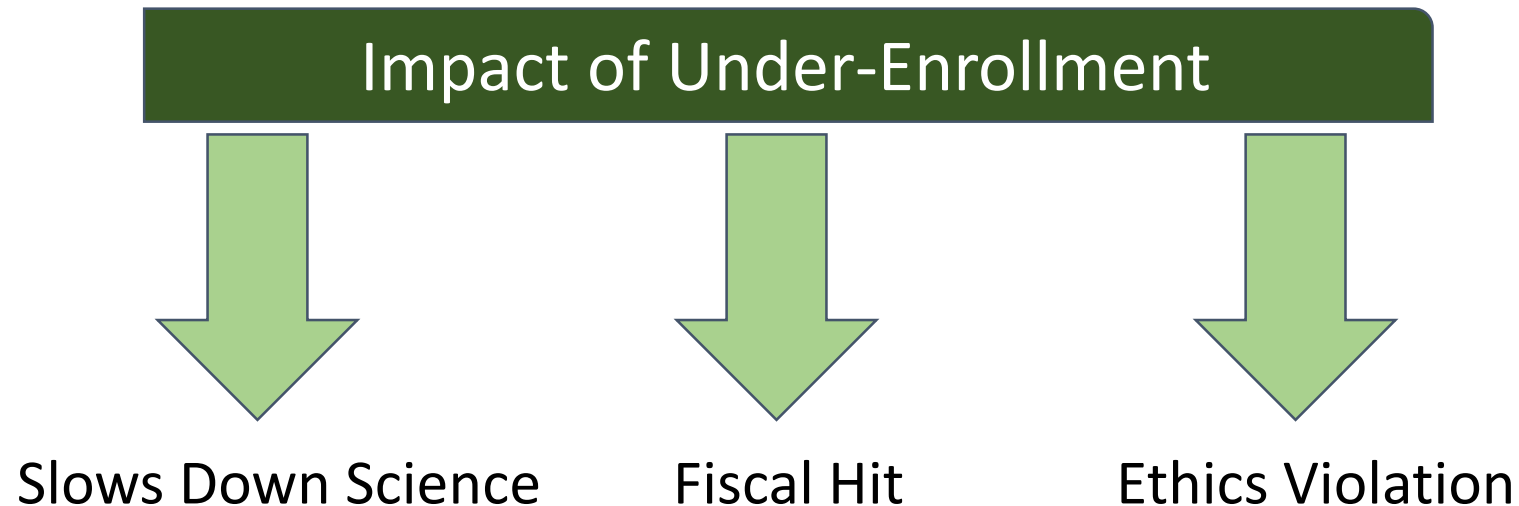
Associate Professor

Obstetrics, Gynecology, and Reproductive Sciences

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Under-Enrollment in Clinical Studies

- Under-enrollment is common
- More pronounced for racial/ethnic minorities, women, older adults, and sexual and gender minorities



Under-Enrollment in Clinical Studies

- OHSU: 837 studies reviewed, 1/3 enrolled only ≤ 1 participant¹
- 50% of non academic study sties enroll ≤ 1 participant²
- 2/3 of all trial sites do not meet enrollment target³

¹Kitterman DR, et al, The prevalence and economic impact of low-enrolling clinical studies at an academic medical center. *Academic Medicine : Journal of the Association of American Medical Colleges*. Nov 2011;86(11):1360-1366.

²Pierre C. Recruitment and retention in clinical trials: What works, what doesn't and why. 2006 Drug Information Association Annual Summit. June 2006

³Tufts Center for the Study of Drug Development

Sample of UCSF Studies

84 studies open for enrollment

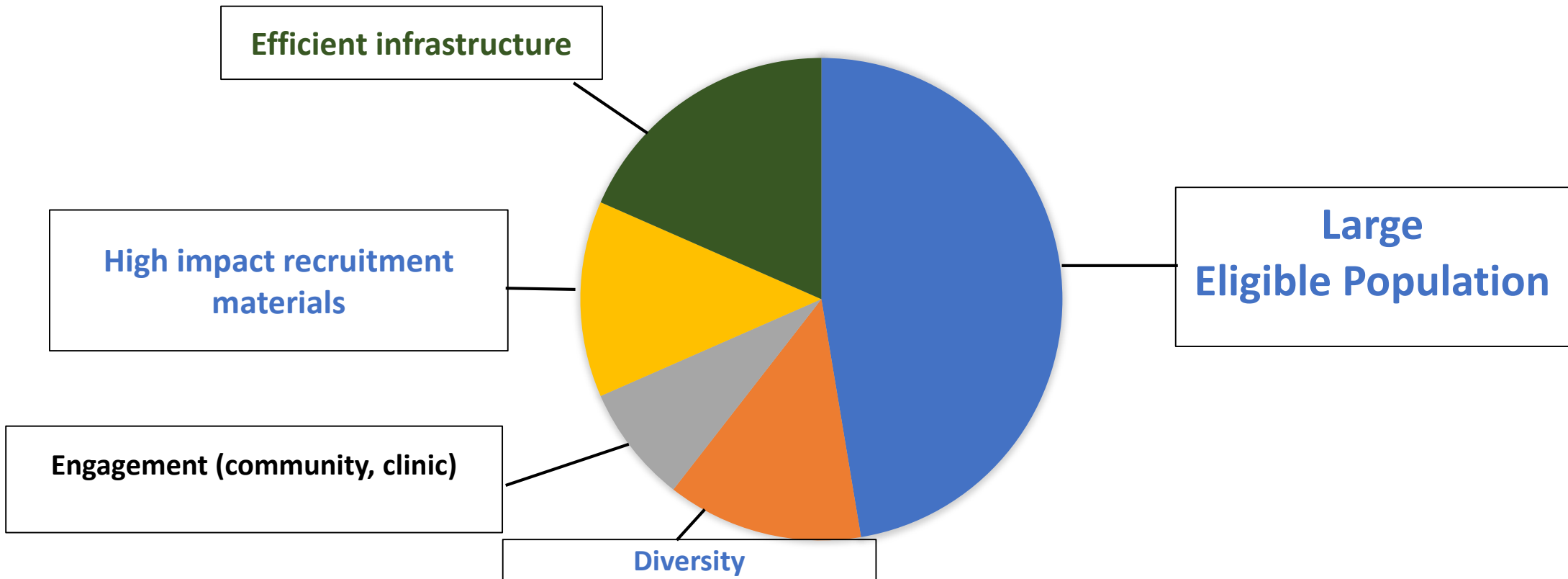
- 79% below enrollment target for timeline
- 18% have no enrolled participants (all open at least 7 months)

81 studies closed from 1/2013-5/2017

- 64% closed without meeting target enrollment
- 14% closed with no more than one participant
- 86% extended enrollment period
- Mean extended enrollment 30 months

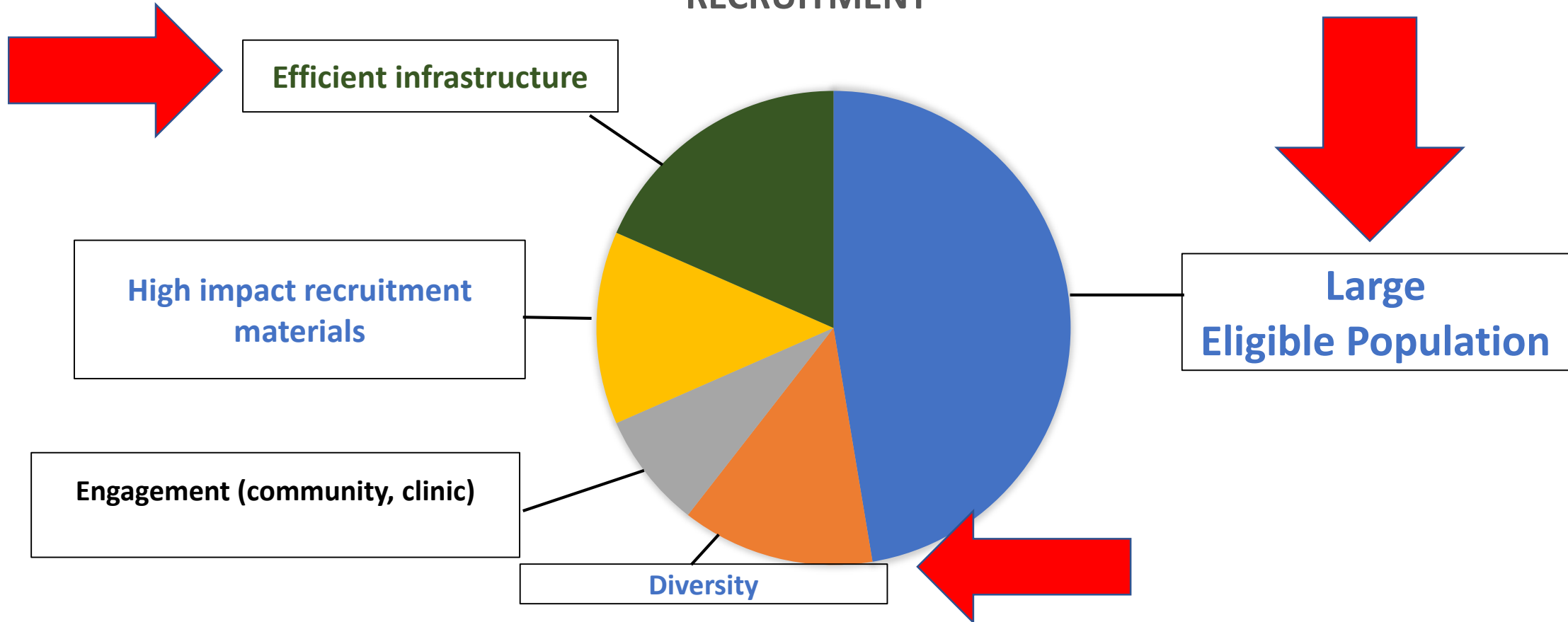
Ingredients for Successful Enrollment

RECRUITMENT



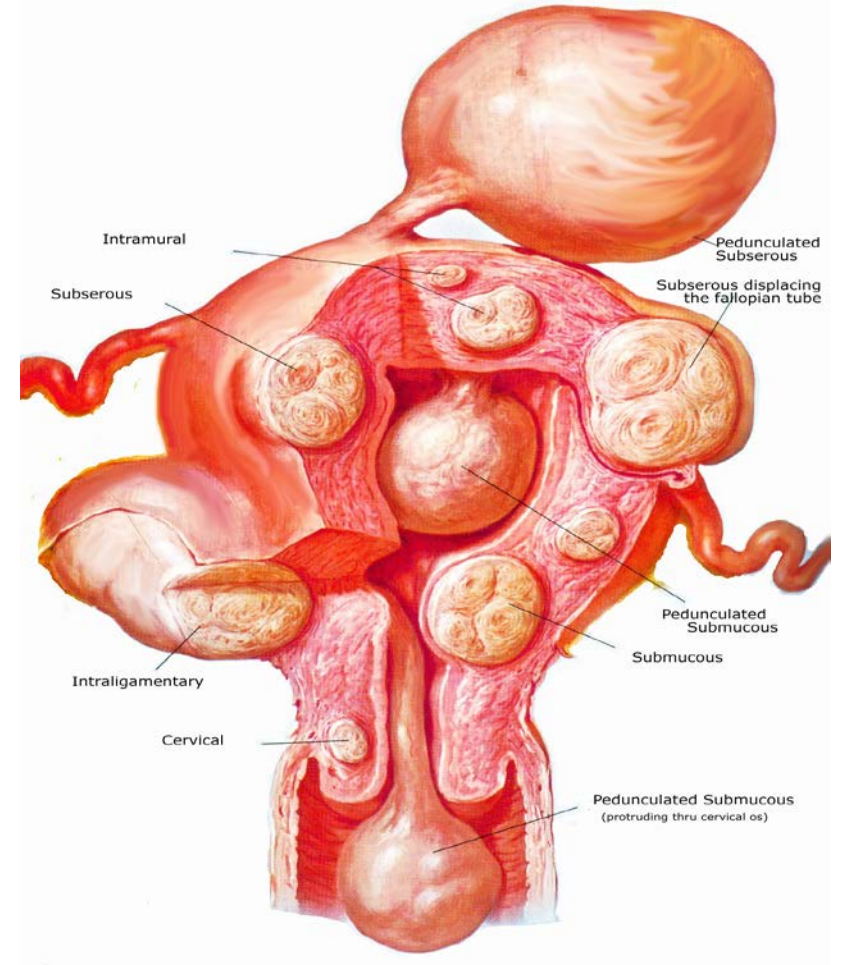
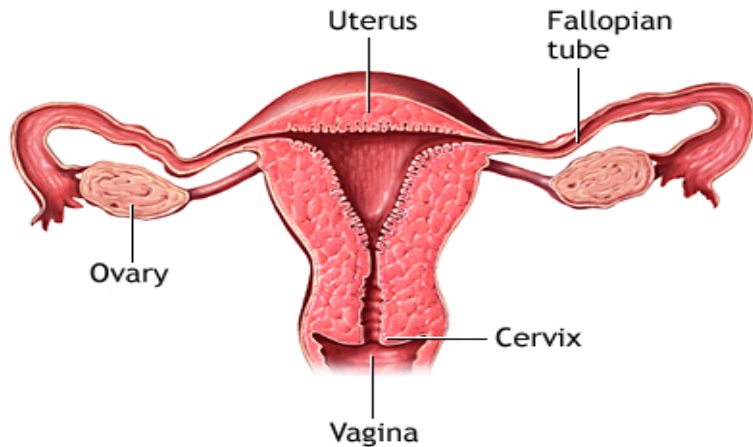
UC Wide Recruitment

RECRUITMENT



UC Wide Recruitment

- Uterine Fibroids: 70% of women by age 50
- #1 reason women undergo major surgery
- \$32 billion/year on treatment



UC Wide Recruitment

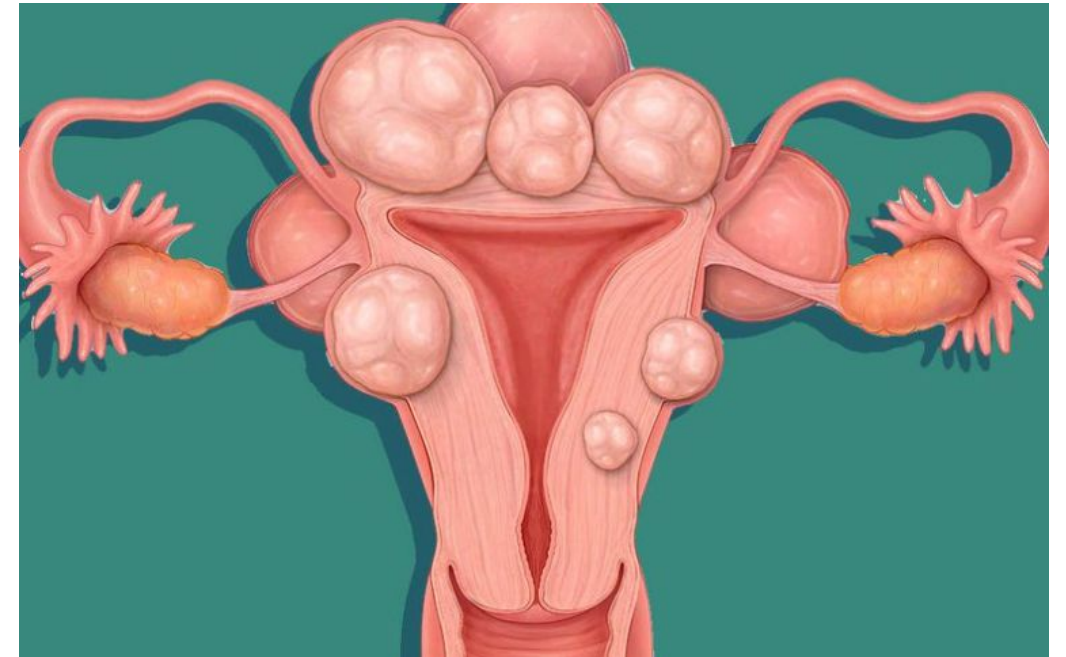
- UC Fibroid Network
- Funding: UCOP and Dept Matching
- AIM: Use the strength of multi-campus collaboration to conduct high impact fibroid studies
- UCSF Coordinating Center

UC Fibroid Network



Benefits of UC wide Recruitment: Fibroids

- Large eligible population:
UCSF fibroid surgery: 450/year
Total UC fibroid surgery: 2,100/year
- Diverse patients and community
Community clinics
Collaborating hospitals
- Efficiency....we hoped!
Centralized infrastructure
Cost containment



Other Benefits of UC wide Studies

- UC Rely for IRB approval
- One contract/admin structure and cost for 5 sites
- All use EPIC (uniform searches for eligible participants)
- UC Brand Identity

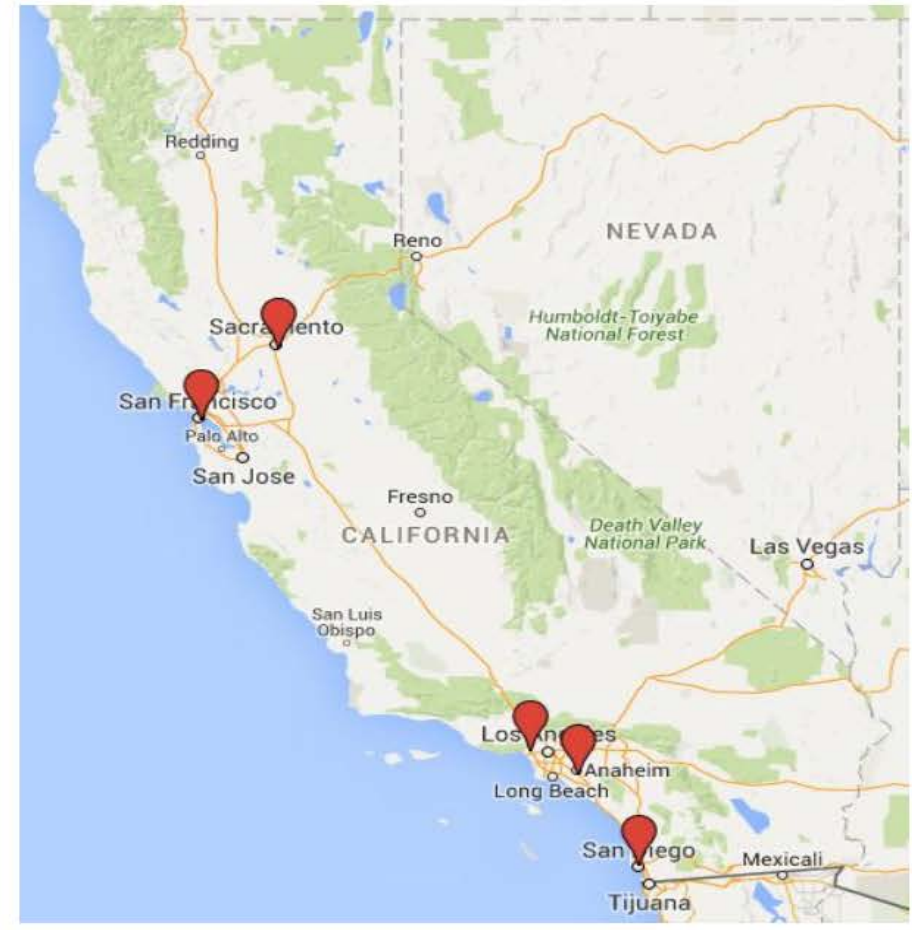
Clinical Benefits of UC wide Recruitment

UC Fibroid Network Members:

- Elaine Waetjen, MD (UC Davis)
- Naghmeh Saberi, MD (UC Irvine)
- Ram Parvataneni, MD (UC Los Angeles)
- Shira Williams, MD (UC San Diego)
- Vanessa Jacoby, MD, MAS (UC San Francisco)

UC Fibroid Centers at individual campuses:

- UC Irvine Uterine Fibroid Services
- UCLA Fibroid Treatment Program
- UC San Diego Fibroid Treatment Program
- UCSF Comprehensive Fibroid Center



Disadvantages of UC wide Studies

- No geographic diversity
- No indirect costs allowed on first \$25,000 of direct costs per UC

UC wide Recruitment: COMPARE-UF

- Fibroid treatment registry, 9 sites (PCORI/AHRQ)
- UC Fibroid Network=ONE site (5 site PIs and Study Coordinators)
- Target enrollment: 500/year



Ideal Recruitment: COMPARE-UF

All Eligible UC Patients



Eligible cohort list sent to UCSF



Recruitment Contact from UCSF: Letter, Email, Call



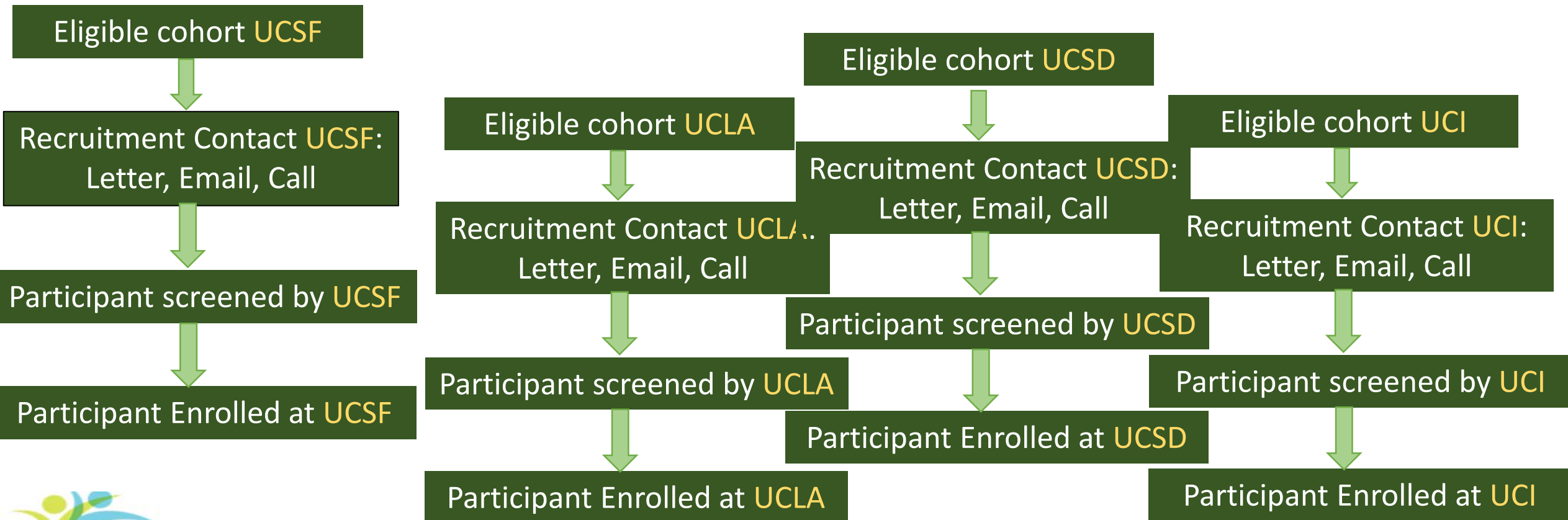
Participant screened by UCSF



Participant Enrolled at Study Site




Actual Recruitment: COMPARE-UF



Patient Experience: UC Wide Branding

- Concern re: recruitment materials from other UC PIs
- 1,700 recruitment letters sent, NO patient complaints



UNIVERSITY OF CALIFORNIA

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University of California,
San Francisco

L. Elaine Waetjen, MD
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Davis

Naghmeh Saberi, MD
University of California,
Irvine

Ram Parvataneni, MD
University of California,
Los Angeles

Shira Williams, MD
University of California,
San Diego

<Month DD, YYYY>

<Full Name>
<Street Address>
<City, State, Zip>

RE: A Clinical Research Study for W

Dear Ms. <Last Name>

I am writing to let you know about t
centered REsults for Uterine Fibro
conducted at the five University of C
Angeles, UC Davis, UC Irvine, and U
about more available treatments for uterine fibroids. You may be eligible to join the study if
you:

To get more information and find out if you are eligible, please call _____ or
email

Thank you for your time.

Vanessa Jacoby, MD
University of California, San Francisco

Ram Parvataneni, MD
University of California, Los Angeles

Shira Williams, MD
University of California, San Diego

L. Elaine Waetjen, MD
University of California, Davis

Naghmeh Saberi, MD
University of California, Irvine

Other Opportunities for UC Wide Recruitment

- Centralized recruitment resources (ad templates, UC wide videoscribe license, UC wide communications to public)
- EMR integration for eligible cohorts
- Volunteer registry (new functions for profiles in EPIC) or UC specific ResearchMatch page
 - many studies conducted remotely

Next Steps

- Potential for major impact on recruitment given large, diverse population
- Need to improve capacity for UC wide recruitment
 - Develop policies (privacy, IRB, compliance, IT, etc)
 - Create protocols
 - Establish infrastructure
 - Promote to investigators
- Align with developments in UC Wide EMR Data