

NIH HEAL

Virtual Workshop on Health
Equity

The incidence of patient availability *sharply decreases* when a clinical trial begins and *returns to its original level* as soon as the trial is completed.

—Lasagna's Law

Why is diversity crucial for clinical research?

- 1 in 5 FDA approvals differed in exposure / response as a function of racial / ethnic group (Ramamoorthy et al., 2015)
- Representation issues particularly acute in precision / personalized medicine (Jackson et al., 2016; Landry et al., 2018)
- Selection and survival biases skew estimates of causal factors (Mayeda 2018; Weuve 2015)

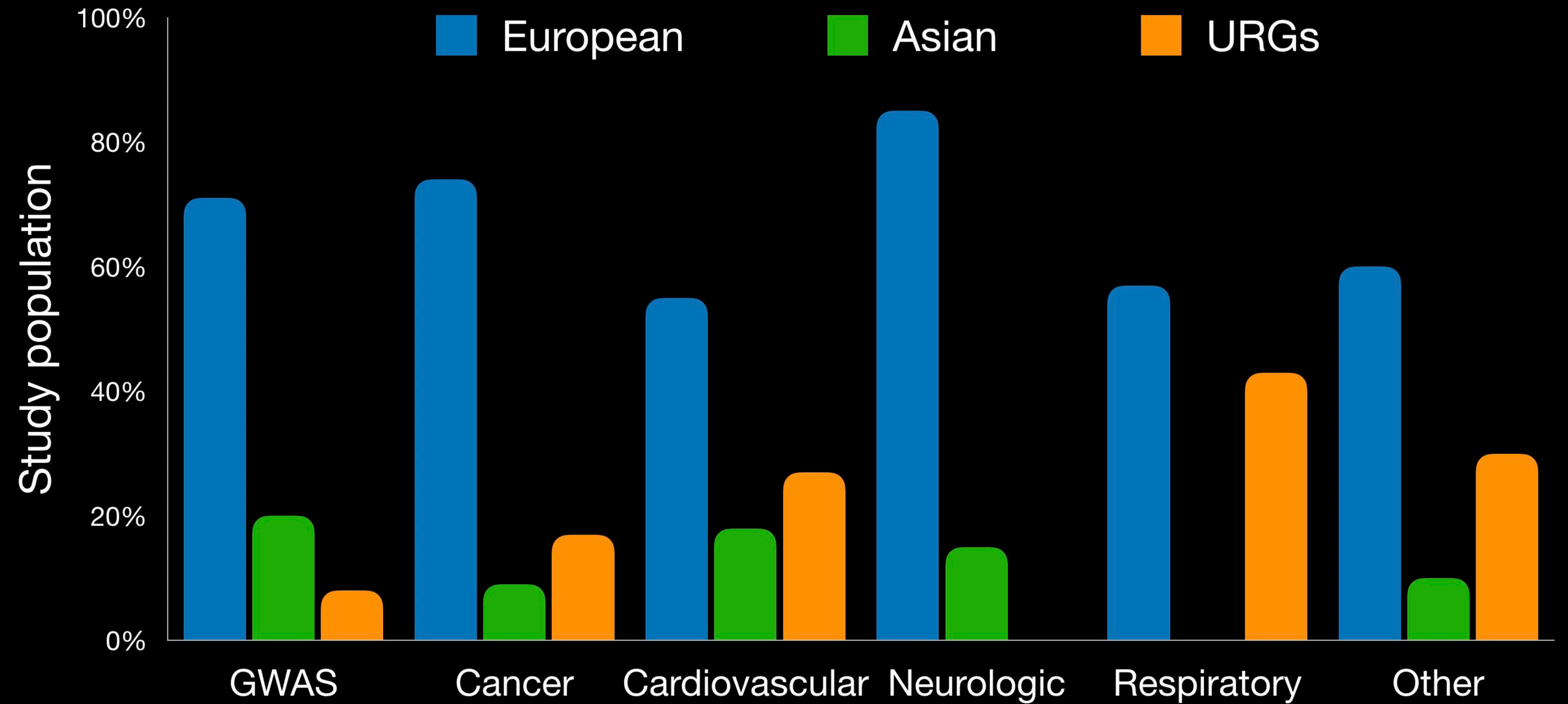


Table 1. Demographic Subgroups in 2019

| DEMOGRAPHIC SUBGROUPS | WOMEN | WHITE | BLACK or AFRICAN AMERICAN | ASIAN | HISPANIC | AGE 65 AND OLDER | UNITED STATES |
|------------------------------|--------------|--------------|----------------------------------|--------------|-----------------|-------------------------|----------------------|
| AVERAGE | 72% | 72% | 9% | 9% | 18% | 36% | 40% |

*Data presented in this report are from 49 snapshots as one drug was approved for two indications.

| | | | | | | | |
|--------------------------------|--------------|--------------|--------------|-------------|--------------|--------------|-------------|
| Est US pop | 50.8% | 76.5% | 13.4% | 5.9% | 18.3% | 16.0% | |
| Median DTS | 55% | 78% | 3% | 5% | 8% | 11.5% | 36% |
| CoV DTS (SD / mean) | 0.47 | 0.35 | 1.64 | 1.44 | 0.85 | 1.10 | 0.80 |

The state of diverse recruitment

- Numerous peer-reviewed manuscripts across every discipline
 - Field is fragmented: no clear definitions, data ontology, comparative effectiveness
 - Most articles focus on single-site case studies, metrics focus only on enrollment
 - Conclusions tend towards advice that is difficult to operationalize, replicate, measure
- Confounds abound
 - Is most of diverse recruitment just the byproduct of charismatic, underpaid CRCs?
 - (What is a “minority,” even?)
 - We fail to de-confound “available” from “accessible”
 - Conflation of outreach, recruitment, retention, engagement activities
- Infrastructure is largely absent
 - Few experts, tools, resources available in generalizable, scalable form
 - Study staff is rarely dedicated to recruitment
 - Engagement and recruitment are entirely separated from most study protocols

Recruitment as a workflow problem

Sampling frame

Lack of awareness of research opportunities

Awareness

Deep mistrust of healthcare system and research

Confusion and concern over what research is

Engagement/Trust

Limited transportation options / times

Interest/Education

Inclusion / exclusion criteria

Lack of plain language use in documents

Return of Value

Fear of placebo / fear of intervention

Screening

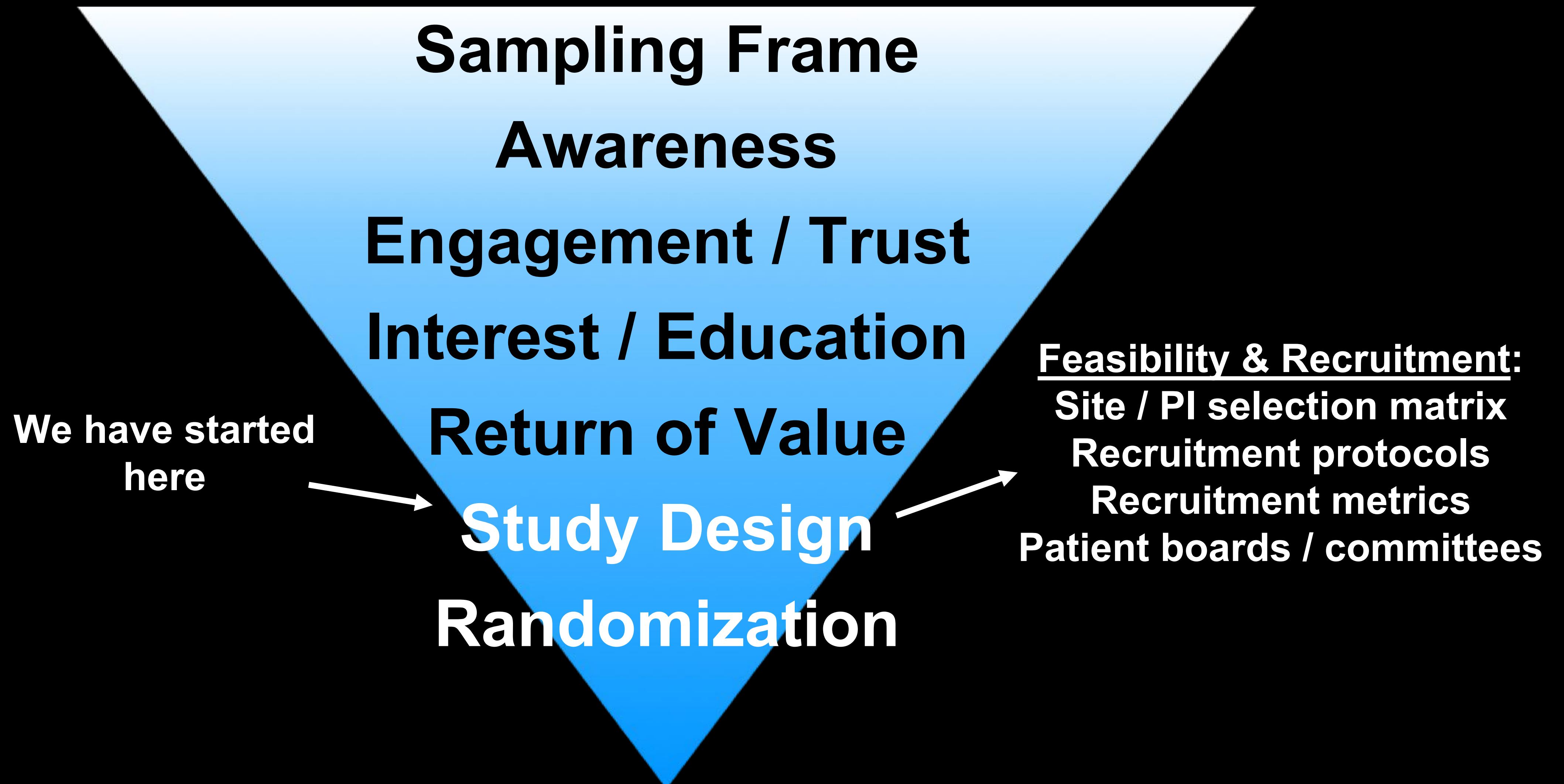
Health insurance coverage

Limited diversity on study staff

Randomization

Insufficient return of value

Example: EPPIC-Net Initiatives



EPPIC-Net Recruitment Initiatives

