

## **Cardiovascular Round Table**

# Plenary meeting on "The Future of Clinical Trials: towards Diversity and Inclusion"

## **SUMMARY SLIDES**

5&6 July 2023



## **CHAIRS**

#### **Academic Event Co-Chairs:**

- Prof Thomas F. Lüscher, ESC President-Elect & CRT Co-Chair
- Dr. Harriette Van Spall, McMaster University Hamilton
- Prof. Faiez Zannad, Centre Hospitalier Régional et Universitaire de Nancy-France

#### **Industry Event Co-Chairs:**

- Dr Kristine Buchholtz, Novo Nordisk VP Global Medical Affairs, OSCD
- Prof. Martin Cowie, AstraZeneca VP Clinical CV and Heart Failure, Late CVRM, Biopharmaceuticals R&D
- Dr Alexandra Goncalves: Bristol-Myers Squibb (BMS)- Head of Digital Health & CRT Co Chair
- Dr André Ziegler, Roche Diagnostics Clinical Science Leader CV Diseases

### Factors associated in under-enrollment



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# Suboptimal recruitment and consent processes

- Recruitment in inaccessible ambulatory settings
- Lack of cultural competence in recruitment and consenting processes
- Inability to address participant concerns
- Language and cultural barriers



# Restrictive eligibility criteria

- Unjustified exclusion of women (including those pregnant or lactating), older adults or children
- Ineligibility due to comorbidities or language barriers



## Burdensome follow-up processes

- High time and cost of attending in-person visits
- Inadequate compensation for trial participation
- Patient financial or caregiving responsibilities



# Homogeneous trial leadership

- Trial leadership teams composed of men-only researchers
- Trial leaders geographically based in Europe and/or North America



## Inadequate regional research capacity

- Insufficient research funding
- Lack of research infrastructure - health information technology, biobank, laboratory capacity
- Inadequate research expertise, networks, collaborations



# The time is now: Designing representative trials Cardiovascular Round Table





#### Targeted, culturally competent recruitment

- Create accessible and
- Use clinic-based, communitybased and virtual recruitment
- Consider adaptive
- Provide cultural competency training for frontline
- Select recruitment sites



#### Inclusive eligibility and consent

- Eliminate unjustified
- Avoid using language, education level, cognitive ability and socio-economic status as eligibility criteria
- Use person-centered consent process including digital consent
- Consider inclusion of next of kin or informal caregivers in discussion



#### Patient-centered processes

- Engage with community advisory boards and patient advocacy groups
- Minimize and reimburse costs of participation
- Offer virtual follow-up and flexible clinic hours
- Consider integration of trial with registry or administrative data to determine clinical outcomes



#### Diverse trial leadership

- Ensure equal access to training, mentorship, funding and advancement opportunities for underrepresented researchers
- Build diverse collaborative networks with attention to gender, geography, ethnicity



#### Stronger research infrastructure

- Promote research readiness
- Collaborate with local citizens to identify barriers to participation
- Invest in electronic medical research records. research facilities. databases and other resources that strengthen research capacity



#### **Scientists**

- Implicit bias training
- Avoidance of gender stereotyping
- Diverse research teams
- Equal opportunity
- Harassment-free culture

#### **Grant Agencies**

- EDI policies
- Charters with academic institutions
- Diverse reviewers
- Transparent reporting

#### Industry

- EDI policies
- Open calls, objective criteria for trial leadership
- Equal pay
- Transparent reporting

#### **Catalyzers**

- Advocacy
- Talent directories
- Research networks
- Training, mentorship, sponsorship

#### **Academic Institutions**

- EDI policies
- Open calls and objective criteria for recruitment, advancement, and internal funding
- Transparent reporting

#### Journals

**Ending Gender Inequality** 

in CV Clinical Trial Leadership

- EDI policies
- Diverse editorial board

- Advocacy
- Funding contingent on diverse research teams
- Research education



Van Spall HGC, Lala A, Deering T et al. JACC 2021 https://www.jacc.org/doi/abs/10.1016/j.jacc.2021.04038

**ESC** 

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with amendment

