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

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

Filbea L, Zhu J, Zannad F, Van Spall HGC. Eur Heart J January 2023
The time is now: Designing representative trials

Targeted, culturally competent recruitment
- Create accessible and multilingual recruitment material
- Use clinic-based, community-based and virtual recruitment
- Consider adaptive recruitment strategies
- Provide cultural competency training for frontline personnel
- Select recruitment sites strategically

Inclusive eligibility and consent
- Eliminate unjustified exclusion criteria
- 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 under-represented 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

Filbea L, Zhu J, Zannad F, Van Spall HGC. Eur Heart J March 2023
Van Spall HGC, Lala A, Deering T et al. JACC 2021
with amendment