



## Global Spotlights

# Strategies for rejuvenating clinical trialists' leadership

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## Foreword

Successful clinical trial leadership requires competencies in trial design, analysis, and interpretation, as well as in reporting and dissemination of trial results, involving scientific, ethical, methodologic, publishing, and lecturing expertise. Additionally, leadership is needed to be able to oversee the execution of trials, collaborate to engage research partners in all aspects of the work, and negotiate and manage interaction with diverse stakeholders and participants. Communication is essential to ensure an effective interaction between trial teams and participants and to clearly report and disseminate research findings.<sup>1</sup> These clinical trial research competencies need to be facilitated among the young and early-career clinical scientists through specific training and interaction with leading experts in the field. Early-career scientists are expected to be proactive and apply and register in research directories, attend networking events, and seek mentorship/sponsorship from the expert trialists.<sup>1</sup>

Furthermore, women remain underrepresented as cardiovascular (CV) specialists and as leaders of CV randomized controlled trials (RCTs), despite several calls towards mitigating these inequalities.<sup>1,2</sup> Recent data have highlighted that participation of clinical trial academic leaders who are of a certain demography may be more successful in improving patient diversity.<sup>3</sup> Increasing sex, ethnic, and geographical diversity in clinical trial leadership and among site investigators, using innovative approaches to participant recruitment and monitoring, may narrow the sex/diversity gap in CV clinical trial participants. A recent meta-analysis reported that among 158 200 participants in 157 RCTs investigating heart failure, only 18.5% were non-White, and female presence within the trial's leadership was associated with twice the odds of the reporting of race and ethnicity data.<sup>3</sup>

## Training future clinical trialists

The need to bolster clinical trial experience among CV fellows and junior faculty is ever-increasing, and yet options to pursue rigorous training

and solid experience in clinical trials are limited. To this end, the MSc in Clinical Trials is a postgraduate course proposed by the European Society of Cardiology that provides participants with in-depth training and understanding of how to plan and conduct randomized clinical trials. One of the objectives of the Cardiovascular Clinical Trials (CVCT) Forum is to promote the young leaders of the future in clinical trial research. To this end, the CVCT Forum leadership has created the CVCT Young Trialists (CVCT-YT) grant and the CVCT Future Trialist (CVCT-FT) fellowship, with the overarching objective of educating a new generation of investigators in the CV field. The aim of these initiatives is to cater the needs for improving skills on clinical trial performance and comprehension.

## How and where to fulfil these aims

The CVCT Forum assembles the most diverse group of stakeholders, discussing trials' rationale, design execution and operational issues, statistical interpretation, clinical meaning, approvability by major regulatory agencies, valuation by payers and health technology agencies, translation into practice guidelines, and implementation in real life by physicians.

The Global CVCT Forum is held annually in Washington, DC (USA). Over the years, it has attracted an audience from over 30 different countries. The CVCT faculty constitutes 40% of the attendees, allowing easy access of young fellows to the highest-level senior environment.

The Forum encourages knowledge sharing between participants as CVCT seeks to familiarize practitioners and investigators with the science of clinical trials from protocol design to result interpretation. Further, the CVCT Forum places attendees in direct contact with primary investigators and senior trial scientists, as well as research and development experts from pharmaceutical/device companies and experts from regulatory agencies. This year's 2023 edition will be a special one since CVCT will be celebrating its 20th anniversary.

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**Figure 1** Cardiovascular Clinical Trials Future Trialists at the 20th Cardiovascular Clinical Trials Forum meeting held in Washington, DC (USA). From left to right: Kieran Docherty, Nicolas Girerd, Jesper Jensen, Enrico Ferro, Alberto Aimò, Matthew Lee, Pieter Martens, Bertram Pitt (faculty), F.Z. (faculty), G.M. (Cardiovascular Clinical Trials Future Trialist coordinator), Jawad H Butt, Ahmed Kolkailah, Tor Biering-Sørensen, Masatake Kobayashi, and Joao Ferreira.

The distinct features of CVCT training opportunities offered to future trialists<sup>4</sup> are (i) learning at master classes organized at each annual Forum by leaders in clinical trial methodology and statistics; (ii) attending or participating as a faculty member at the annual Forum scientific sessions; (iii) networking with critical trials' stakeholders; (iv) hands-on training, beyond theoretical courses, participating as a full member in major trial's steering committees; and (v) promoting diversity among future trialists with emphasis on gender and racial/ethnic diversity, partnering with organizations dedicated to this endeavour, such as Women As One.

The CVCT 'Career Escalator' initiative at the CVCT Forum provides the rare and unique opportunity for young fellows of having one-on-one speed dating conversations with selected senior principal investigators/mentors with ample experience in clinical trials.

The CVCT-YT grant is aimed at facilitating attendance of young fellows to the CVCT Forum.

The CVCT-FT fellowship, supported jointly with industry partners and also the US NHLBI, seeks to provide young fellows (*Figure 1*) with the necessary skills to lead clinical trials by engaging with major principal investigators and mentor trialists as a 'steering committee mentee', joining the steering committee of an ongoing major clinical trial as a full member, learning about the conduct of the trial and data collection,

analyses, and interpretation, and co-authoring with the trial leadership secondary trial manuscripts. The fellowship also allows for the opportunity to take part in internal scientific and operational training as applicable for the role, including being invited to the CV outcome trial review meetings of ongoing large clinical trials in the CV–metabolic–renal axis. The interactions of the CVCT-FT in the internship should be broad, interacting with the company representative—but also with the academic faculty in the trials' oversight committees.

Applications to the CVCT-YT grant and the CVCT-FT fellowship are open to fellows in training in the field of CV diseases.<sup>4</sup>

## Modes of selection and monitoring

The CVCT-FT review committee is comprised of CVCT leadership and industry partner representatives. Selection of candidates is based on expression of interest, willingness, preparedness, scientific merit, and professional scheme. The programme is monitored through face-to-face or teleconference personal interviews with the future trialist, during the year of training. The selected CVCT-FT may be invited to present regarding his/her experience and findings (if original data analyses are undertaken) at the annual CVCT Forum sessions.

## Conclusions

In summary, initiatives seeking to train future clinical trial leaders are much needed. Young cardiologists and fellows in training should be offered more specific opportunities to train as future trialists. Young fellows with an interest in clinical trials, both in-training and mid-career faculty, could benefit from the multiple training initiatives developed by the CVCT Forum.

## Listing of past and current Cardiovascular Clinical Trials Future Trialist

Coordinator: G.M. (Spain)

Past and current CVCT Future Trialists: Alberto Aimò (Italy), Tor Biering-Sørensen (Denmark), Jawad Haider Butt (Denmark), Kieran Docherty (UK), Joao Ferreira (Portugal), Enrico Ferro (USA), Prakriti Gaba (USA), Nicolas Girerd (France), Jesper Jensen (Denmark), Muhamad Shahzeb Khan (USA), Darae Ko (USA), Masatake Kobayashi (Japan), Ahmed Kolkailah (USA), Matthew Lee (UK), Xavier Rossello (Spain), G.M. (Spain), Pieter Martens (Belgium), Brendon Neuen (Australia), Antony Peters (USA), Elke Platze (USA), Yogesh Reddy (USA), Gianluigi Savarese (Sweden), and Dominique Vervoort (Canada).

## Declarations

### Disclosure of Interest

G.M. declares being a member of the Steering Committee of the Hermes Novo Nordisk clinical trial. F.Z. reports personal fees from 89Bio, Applied Therapeutics, Bayer, Boehringer, BMS, CVRx, Cardior, Cereno Pharmaceutical, CellProthera, CEVA, KPB, Merck, Novartis, Novo Nordisk, Owkin, Pfizer, Otsuka, Roche Diagnostics, Servier, US2.2 having stock options at G3Pharmaceutical and equities at Cereno Pharmaceutical, Cardiorenal, Eshmoun Clinical Research, and being founder of Cardiovascular Clinical Trialists.

### References

1. Van Spall HGC, Lala A, Deering TF, Casadei B, Zannad F, Kaul P, et al. Ending gender inequality in cardiovascular clinical trial leadership: JACC review topic of the week. *J Am Coll Cardiol* 2021;**77**:2960–72. <https://doi.org/10.1016/j.jacc.2021.04.038>
2. Cho L, Vest AR, O'Donoghue ML, Ogunniyi MO, Sarma AA, Denby KJ, et al. Increasing participation of women in cardiovascular trials: JACC council perspectives. *J Am Coll Cardiol* 2021;**78**:737–51. <https://doi.org/10.1016/j.jacc.2021.06.022>
3. Wei S, Le N, Zhu JW, Brethett K, Greene SJ, Mamas MA, et al. Factors associated with racial and ethnic diversity among heart failure trial participants: a systematic bibliometric review. *Circ Heart Fail* 2022;**15**:e008685. <https://doi.org/10.1161/CIRCHEARTFAILURE.121.008685>
4. <https://www.globalcvctforum.com/future-trialists>.