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► **To cite this version:**

Guiomar Mendieta, Faiez Zannad. Strategies for rejuvenating clinical trialists' leadership. European Heart Journal, 2024, 10.1093/eurheartj/ehad851 . hal-04390490

HAL Id: hal-04390490

<https://hal.univ-lorraine.fr/hal-04390490v1>

Submitted on 12 Jan 2024

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Strategies for rejuvenating clinical trialists' leadership

Short Title: CVCT Future Trialist fellowship

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Word count: 1,016/1,000

FOREWORD

Successful clinical trial leadership requires competencies in trial design, analysis, 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 oversight 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 findings¹. 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 trialists¹.

Furthermore, women remain underrepresented as cardiovascular (CV) specialists and as leaders of CV randomized controlled trials (RCTs), despite several calls towards mitigating these inequalities^{1,2}. Recent data have highlighted that participation of clinical trial academic leaders who are of a certain demography may be more successful in improving patient diversity³. Increasing sex, ethnic and geographical diversity in clinical trial leadership and amongst 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 data³.

TRAINING FUTURE CLINICAL TRIALISTS

The need to bolster clinical trial experience amongst 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 randomised 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 FULFILL 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 (United States). 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.

The distinct features of CVCT training opportunities offered to future trialists⁴ 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 endeavor, such as WomenAsOne.

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 CVDs⁴.

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 program 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.

CONCLUDING REMARKS

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 & CURRENT CVCT-FT

Coordinator: Guiomar Mendieta (Spain).

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

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4. <https://www.globalcvctforum.com/future-trialists>



FIGURE LEGENDS

Figure 1. CVCT Future Trialists at the 20th CVCT Forum meeting held in Washington DC (United States). From left to right: Kieran Docherty, Nicolas Girerd, Jesper Jensen, Enrico Ferro, Alberto Aimo, Matthew Lee, Pieter Martens, Bertram Pitt (Faculty), Faiez Zannad (Faculty), Guiomar Mendieta (CVCT Future Trialist Coordinator), Jawad Haider Butt, Ahmed Kolkailah, Tor Biering-Sørensen, Masatake Kobayashi and Joao Ferreira.