



CARDIOVASCULAR ROUND TABLE

Briefing Document
April 2020

Table of Contents

1	<u>BACKGROUND.....</u>	<u>3</u>
2	<u>FORMAT.....</u>	<u>3</u>
3	<u>COMPOSITION AS OF APRIL 2020</u>	<u>6</u>
4	<u>ACTIVITIES</u>	<u>6</u>

1 BACKGROUND

The Cardiovascular Round Table was founded on February 8th 2001 in Amsterdam with the specific mission to provide a unique forum for high level dialogue between industry (pharmaceuticals, devices and equipment) and society leadership.

Its aim is to identify and discuss key strategic issues for the future of cardiovascular health in Europe and develop long term partnerships with Industry.

This to allow the ESC to leverage its unique position as a broker between professionals, industry and where appropriate any relevant third parties in order to become a key strategic force in cardiovascular health in Europe. In addition the CRT is meant to serve the ESC as a 'think-tank' in which through listening, understanding and learning from each other, strategic priorities for the ESC and its future can be set.

The structure of the CRT assumes senior representatives from companies, ESC board and ESC staff. The uniqueness and strength of the CRT forum consists of the fact that this is a joint collaboration to identify issues that are relevant to all parties, discuss long term strategies on how to approach these issues and agree on joint recommendations for further actions.

Specifically the collaboration is not aimed at seeking (financial) support from the industry for any given project, but that actions or projects resulting from CRT meetings will be delegated for implementation to for instance departments within the HH, academic centres or industry centres.

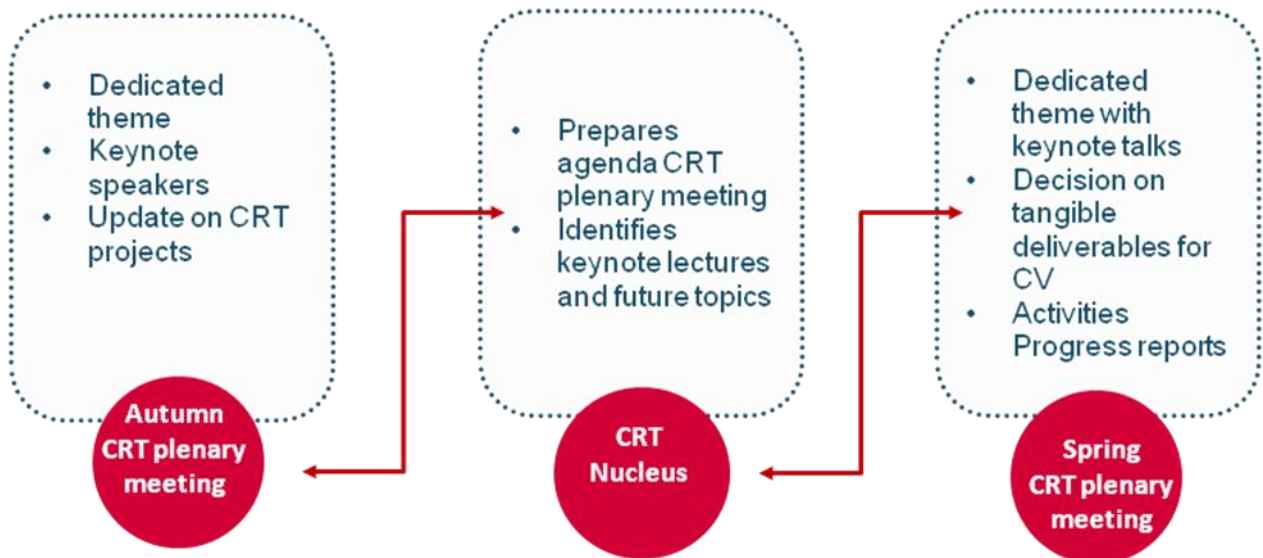
2 FORMAT

- CRT should be preserved as the strategic platform for cardiovascular medicine to identify the issues that will impact the way cardiovascular medicine will be run over the next decades
- To enable high level strategic discussions, the seniority of the CRT should be secured, therefore only **senior representatives** from both ESC as Industry should be present at the CRT plenary meetings
- **ESC is represented by** the members of the ESC Board (including the Presidents of the Associations) as well as relevant experts in a particular field of interest for the CRT.
- **CRT Co-chairs:** The CRT plenary is co-chaired by an ESC and an Industry representative. For the ESC, this is the President-Elect.
- In 2018 an election process was put in place to appoint the next industry co-chair, since Dr Stefan Schroeder's mandate was to end in May 2019.
- As a result of the election, Dr Isabelle Richard-Lordereau, from Amgen, was elected in January 2019. She joined the Nucleus and was involved in CRT activities until officially taking over the CRT co-

chairing at the Spring 2019 plenary meeting, for a 3-year mandate.

- A **CRT Nucleus Group** oversees the CRT activities and is composed of ESC leadership, CRT co-chairs, and representatives from each industry sector.
- Decision was made by the Nucleus in January 2019 to expand the number of industry representatives to 6 members, in addition to the co-chair, versus 4 previously.
- An election took place in July 2019 to appoint *3 new members*.
- It was also agreed to set the duration of the Nucleus members mandate to 3 years, with a staggered term, and a renewal of 50% seats in each election, together with a maximum of 2 out of the 3 seats being allocated each time to the individuals working for a company in the Pharma sector, to guarantee a fair representation of the 3 industry sectors.
- Seats are allocated to individuals, not companies: if a member leaves his/her company and does not join another member company of the CRT, his/her seat will be vacant until next election
- **The composition of the Nucleus as of April 2020 is:**
 - **ESC:** CRT co-chair + 4 ESC members :
Professor M. Cowie, Prof. G. Hindricks, Prof. M. Lettino and Prof. J. Mascherbauer
 - **Industry:** CRT co-chair + 6 members representing the 3 industry sectors. The past industry co-chair is entitled to remain within the Nucleus as Advisor :

Dr A. Goncalves (Philips), Prof. A. Himmelmann (AstraZeneca), Dr Matias Nordaby (Boehringer-Ingelheim), Dr David Soergel (Novartis), Prof. M. Thoenes (Edwards Lifesciences), and Dr A. Ziegler (Roche Diagnostics).
[Dr Stefan Schroeder, past industry co-chair, remained in the Nucleus until his retirement from Bayer in March 2020].
- The **CRT** meets twice a year: a two-day plenary meeting in Spring and a one-day meeting in Autumn.



- Strategic discussions at the CRT plenary meeting may be implemented through **practical action items**.
- When relevant, the practical action items are carried out through **dedicated workstreams / project teams**, which involve experts in the relevant fields from both ESC as Industry and are set up to deliver the objectives defined by the CRT plenary meeting.
- Project teams should carry out the brief received by the CRT plenary group and deliver their objective within a **determined period of time**
- **Communication:** in between CRT plenary meetings, a newsletter is sent to all CRT members to provide them with an update on any relevant CRT, ESC and EU news.
- **CRT Company Membership fee** represents 40K/Year

3 COMPOSITION – APRIL 2020 - 21 COMPANIES

Abbott	MSD
Alnylam	Novartis Pharma
Amgen	Novo Nordisk
AstraZeneca	Pfizer Inc
Bayer	Philips
Boehringer-Ingelheim	Roche Diagnostics
Bristol-Myers Squibb	Sanofi
Daiichi-Sankyo	Servier International
Edwards Lifesciences	Siemens
GE Healthcare	Vifor Pharma
Medtronic	

4 ACTIVITIES – CRT PROJECTS

When relevant, CRT Projects, once approved by the Nucleus and the Plenary Group, are developed within small groups, “workstreams”.

Some activities have a more permanent nature, such as the “Regulatory-R&D workshops”, which are now flagship projects of the CRT.

4.1 Some of the former workstreams topics:

4.1.1 Championing innovation: In this workstream, the CRT addressed possible causes for the loss of cardiovascular-related R&D activity and productivity, and established a series of actions designed to close the innovation gap.

<p>Pharmaceutical sector: July 2013 : EHJ Publication “Championing cardiovascular health innovation in Europe” white paper+ communication/dissemination campaign towards National Cardiac Societies Presidents and Editors-in-chief, as well as European Commission.</p>	<p>Technology sector: July 2015: EHJ Publication “Barriers to cardiovascular device innovation in Europe” white paper</p>
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4.1.2 eHealth:

eHealth, defined as “the use of Information & Communication Technologies in healthy living and healthcare”, will become a reality, supported by massive investments from European and US governments. And a professional society such as the ESC should secure a role in the decision making process.

A project group was formed to identify what e-health means for the ESC, and which aspects of this very broad term should be on the CRT/ESC radar screen for engagement.

2 back-to-back workshops were organized in ESC Brussels offices in April 2014

<p>A large (30+) stakeholders meeting under CRT umbrella Industry members, ESC members, Experts, EU Commission representatives (DG Sanco)</p>	<p>A meeting with ESC senior members to determine ESC strategy and tactics and define an ESC roadmap for eHealth.</p>
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Publication of an ESC position paper in the European Heart Journal in August 2015 and definition of an ESC Roadmap -

- CRT Plenary Meeting on eHealth in October 2015.
- eHealth unit created within the ESC European Heart Agency in Brussels.
- Digital Health Committee created in 2018.

4.1.3 Quality in CV medicine and clinical outcome

Rationale: There remain important healthcare gaps between evidence based and guideline supported therapeutic strategies and the reality of only partial update of such therapies into practice and a lack of persistence with such therapies over time. The gap could be reduced in better performance healthcare systems and better performance hospitals.

Objective:

- To define the scale of the problem among ESC members countries and to identify treatment gaps that are potentially amenable to change.
- To identify the drivers of change in well-established national and multi-national quality improvement programmes

2 expert meetings in January and June 2015 :

- To collect feedback as well as advice and recommendations
- To help the ESC define priorities for the scope and strategy in the development of new quality improvement initiatives
- Experts involved in large trials, quality improvement programmes or EU-funded projects
- Choice of “ACS” for a pilot programme on quality improvement, based on the evidence from trials, the guidelines and the potential for quality improvement.

Outcome: collaboration with ACCA Association:

- Similar project started within ACCA to define key evidence based quality indicators in the field of ACS
- Consultation and development process completed
- Decision for an alignment between the 2 projects for a stronger impact
- CRT workstream co-chair involved in the finalization of the ESC ACCA Quality Indicators paper and the test of QI in Europe
- Position paper accepted for publication in European Heart Journal: Acute Cardiovascular Care

4.1.4 Patient empowerment / Patient engagement

Rationale:

- Cardiac diseases are still a major cause of early disability and death; Governments focus on prevention rather than treatments implies long term and big size trials; regulators become “risk-averse” and payers require more “real data”.
- Trials are larger and last longer; increasing importance of patient oriented outcomes; difficulty to recruit patients in trials and to keep them.
- Patients voice and influence is becoming pivotal
- Definition of patient engagement (WHO definition) = a process through which people gain greater control over decisions and actions affecting their health

Expert meeting in January 2015, with : Physicians, “Patients like me”, Pharma industry, John Hopkins hospital research network, EMPOWER-EU project, Dutch Heart foundation, EU Heart network

Objectives:

To assess

- needs and on-going initiatives regarding patient empowerment/engagement
- from “physician”, “patient” and “data collection” perspectives

To identify

- the major stakeholders in this process of patient engagement
- gaps from the physicians community perspective

To develop

- recommendations and tools to improve patient engagement in taking care of their health

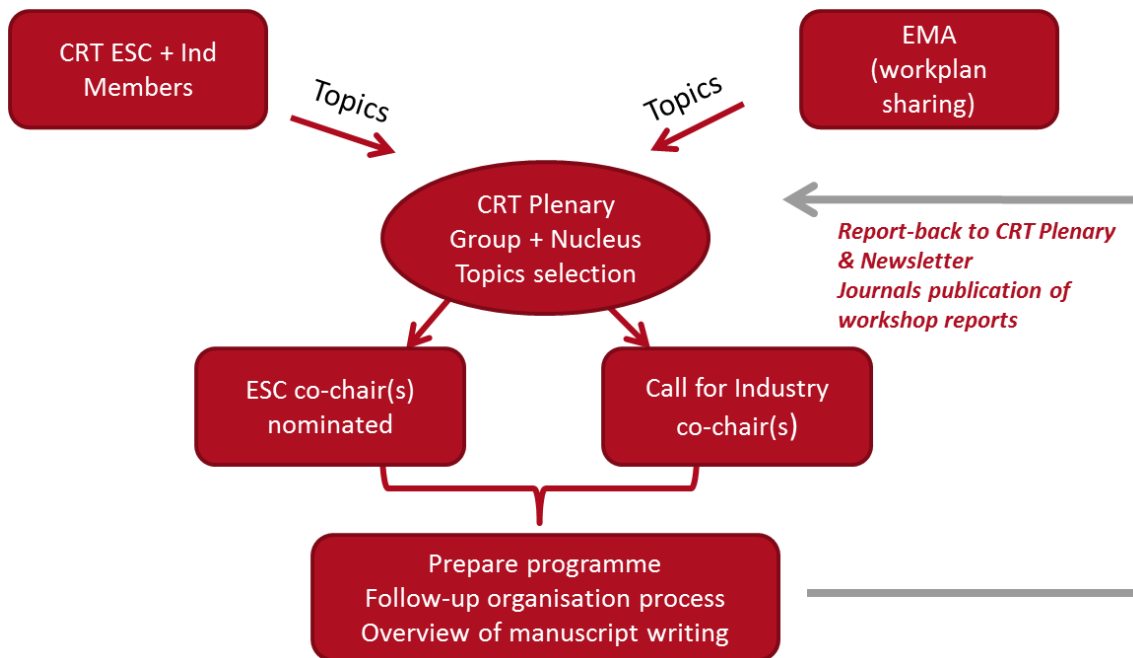
Outcomes:

- Creation of an ESC Taskforce to undertake a thorough review of the opportunities offered by patient engagement to cardiovascular medicine, addressing all aspects of patient engagement:
 - From fundamental prevention education programmes through to recruitment, retention, and compliance of participants in clinical trials.
- ESC taskforce preliminary discussions with influential patient groups to help determine
 - the optimum elements of a comprehensive patient engagement initiative
 - how best to collaborate to ensure that the long-term benefits can be realised.
- Launch of the **ESC Patient Forum in June 2018.**

4.2 R&D and Regulatory Workshops

These have become flagship activities of the CRT

4.2.1 Workflow and Deliverables – Workshop process



4.2.2 R&D focused workshops

To discuss alternative ways to conduct randomised controlled clinical trials and their methodology and to secure ways to encourage innovation.

TOPICS addressed in “R & D Workshops” – 2012-2019		
October 2012	“Health-related quality of life as key outcome parameter in cardiovascular medicine”.	Paper published in EHJ in April 2014
February 2013	"Personalisation of Cardiovascular Medicine: Opportunities and Challenges" Joint workshop ESC European Affairs Committee & CRT	Paper published in EHJ in September 2014

March 2014	“New ideas for the conduct of credible and realistic clinical trials to improve management of chronic cardiovascular diseases “	Report published in EHJ on 16 June 2015
16-17 June 2016	ACS: early diagnosis and consequences	Report published in EHJ 03 October 2017
10 October 2017	Innovation in valvular heart disease therapy	Report published in EHJ in Feb 2019
26-27 June 2019	Development, validation and implementation of Biomarkers in cardiovascular medicine.	Report submitted to EHJ in Jan 2020 – under review

4.2.3 Regulatory-focused Workshops

Rationale

Aligned understanding of clinical experts (eg. Health Care Professionals’ organizations / Learned Societies, regulators & industry) is key to ensure:

- Evolution of well informed regulatory and clinical guidelines
- Robust clinical development plan
- Smooth regulatory assessment

ESC Regulatory Workshops are a unique example of a framework gathering a learned society + industry members + regulatory experts.

They provide a unique opportunity for transparent, constructive dialogue relating to CV related clinical and regulatory matters, without any conflict of interest to participants, and also enabling to engage/align European and US perspectives.

They are highly supported by current stakeholders and will continue to play an important role in advancing development of innovative therapies for a growing CV related health care burden

The objectives of these workshops are:

- Review understanding of CV related conditions.
- Review evolving CV related treatment guidelines & epidemiology
- Early input to concept/ planned CV based regulatory guidance, often upon request from EMA
- Regulatory expectations for licensing decisions
- European focus but opportunities to leverage understanding with US FDA when possible
- Production of a scientific paper

TOPICS addressed in regulatory workshops 2012-2019		
February 2012	“International Differences in Treatment Effect”	EHJ Publication March 2013
June 2012	“Large Streamlined Studies in CVD”	EHJ Publication January 2014
February 2013	“Obesity and CV Implication”	
21-22 January 2015	“Composite & Surrogate Endpoints for CV Clinical Trials in Heart Failure”	Report published in EJHJ April 2016
30-31 March 2015	“Treatment of ACS: Clinical Investigation of New Medicinal Products Future Directions” Topic selected in concertation with EMA in view of their guidelines update.	Report published in the Acute Cardiovascular Care Journal - 29 June 2016
23-24 April 2015	“Electronic Health Records to Improve Patient Care and Facilitate Clinical Research”	Report published in Clinical Research in Cardiology August 2016
12-13 May 2016	"Clinical investigation of medicinal products for the treatment of Chronic Heart Failure" - Topic selected upon request from EMA , in relation to their upcoming CHF Guidelines.	Report published in EJHF March 2017
27-28 September 2016	“Lipid-lowering strategies for reduction of CV risk”	Report published in EHJ Cardiovascular Pharmacotherapy Nov 2017
27-28 March 2017	“Novel Oral Anti Coagulants in Atrial Fibrillation”	Report published in Cardiopulse Aug 2017
13-14 Feb 2018	“Knowledge Gaps in Diabetes and CDV” , in relation to the planned revision of EMA Diabetes Guidelines (issued for public consultation in Jan 2018)	Report published in EHJ Nov 2018
26-27 March 2018	“Stroke” - A workshop developed in collaboration with the ESC Council on Stroke.	Report published in the European Journal of Preventive Cardiology
05 June 2019	“Level of requirement for paediatric studies” – topic in relation to EMA Guidelines on VTE Workshop organized jointly with the Association for European Paediatric and Congenital Cardiology.	No publication Joint ESC/AEPC comments prepared during the meeting were sent to EMA in the framework of their public consultation.

CRT ACTIVITY PLAN 2020 – 2021

With the on-going global pandemic, CRT partners and the Nucleus had to revisit the workplan set for 2020-2021.

Some of the CRT activities planned as of April 2020 will be in new formats and some will be postponed.

Workshop and Plenary Meetings planning 2020-2021		
23-24 Jan 2020 Madrid	Workshop “The Cancer Patient & Cardiology” ESC co-chairs: Prof. Giorgio Minotti and Prof. Jose-Luis Zamorano Industry co-chair: Dr Chirster Gottfridsson (AstraZeneca)	Manuscript-report in preparation
19-20 Feb 2020 Amsterdam	Workshop “Chronic Coronary Syndromes” (in relation to ESC Guidelines on the same topic) ESC co-chairs: Prof. Eva Prescott and Prof. William Wijns (TBC) Industry co-chairs: Dr Isabelle Lordereau (Amgen) and Dr Martin van Eickels (Bayer)	Manuscript-report in preparation
28-29 Apr 2020	Workshop “CV Imaging & Precision Medicine” ESC co-chairs: Prof. Stephan Achenbach and Prof. Sven Plein Industry co-chairs: Dr Claudia Kaiser-Albers (MSD), Dr Alexandra Goncalves (Philips) and Dr Friedrich Fuchs (Siemens)	Postponed to DECEMBER 2020 (date TBC) + Programme to be adapted for an on-line event
25-26 June 2020 Timeframe: First half of June 2020	Plenary Meeting “CVD in the Elderly” New topic selected: “Covid-19 and CVD: a multi-perspective approach”	On-line event
October 2020	Plenary Meeting - Cancelled	
March 2021	Workshop on “Heart Failure” involving EMA and the HF Association of the ESC.	Face-to-face event
12-13 May 2021 (tbc)	Plenary Meeting “CVD in the Elderly”	Face-to-face event
September 2021	Workshop on “Lipids”	Face-to-face event

ANNEX : CRT Composition APRIL 2020

Prof	Barbara	CASADEI	ESC 2018-2020 Board – President
Prof	Jeroen	BAX	ESC 2018-2020 Board – Past President
Prof	Stephan	ACHENBACH	ESC 2018-2020 Board – President-Elect and ESC Co-chair of the CRT
Prof	Cecilia	LINDE	ESC 2018-2020 Board – VP of WGs and Councils, Women in ESC, ESC Membership and Young Communities
Prof	Franz	WEIDINGER	ESC 2018-2020 Board – VP of NCS and Advocacy
Prof	Jose	ZAMORANO	ESC 2018-2020 Board – VP of NCS and Global Affairs
Prof	Gunnar	OLSSON	ESC 2018-2020 Board - Advisor
Mr	Jonathan	SELLORS	ESC 2018-2020 Board - Advisor
Prof	David	ERLINGE	ESC 2018-2020 Board - Councillor Media and E-Communication
Prof	Stephan	GIELEN	ESC 2018-2020 Board - Councillor ESC Young Communities and Advocacy activities related to prevention
Prof	Mikael	GLIKSON	ESC 2018-2020 Board - Councillor ESC Membership and Women in ESC/Diversity within ESC
Prof	Bernard	IUNG	ESC 2018-2020 Board – Councillor Media
Prof	Julia	MASCHERBAUER	ESC 2018-2020 Board - Councillor Women in ESC/Diversity within ESC and ESC Young Communities – Member of the CRT Nucleus
Prof	Zuzana	MOTOVSKA	ESC 2018-2020 Board - Councillor E-communication and ESC Membership
Dr	Susanna	PRICE	ESC 2018-2020 Board – President ACCA Association
Dr	Tina	HANSEN	ESC 2018-2020 Board – President ACNAP Association
Prof	Thor	EDVARSEN	ESC 2018-2020 Board – President-Elect EACVI Association
Prof	Paul	DENDALE	ESC 2018-2020 Board – President EAPC Association
Prof	Andreas	BAUMBACH	ESC 2018-2020 Board – President EAPCI Association
Prof	Hein	HEIDBUHEL	ESC 2018-2020 Board – President EHRA Association
Prof	Petar M.	SEFEROVIC	ESC 2018-2020 Board – President HFA Association
Prof	Lina	BADIMON	ESC 2018-2020 Board – Chairperson Advocacy Committee
Prof	Silvia	PRIORI	ESC 2018-2020 Board – Co-Chairperson Congress Programme Committee

CRT briefing document April 2020

Prof	Marco	ROFFI	ESC 2018-2020 Board – Co-Chairperson Congress Programme Committee
Prof	Stephan	WINDECKER	ESC 2018-2020 Board – Chairperson Clinical Practice Guidelines Committee
Prof	Paulus	KIRCHHOF	ESC 2018-2020 Board – Chairperson Education Committee
Prof	Christopher Peter	GALE	ESC 2018-2020 Board – Chairperson EORP Committee
Prof	Diederick	GROBBEE	ESC 2018-2020 Board – Chairperson Global Affairs
Prof	Donna	FITZSIMONS	ESC 2018-2020 Board – Chairperson Patient Engagement
Prof	Thomas	LUESCHER	ESC 2018-2020 Board – Chairperson Publications Committee
Prof	Thomasz	GUZIK	ESC 2018-2020 Board – Chairperson Research and Grants Committee
Dr	Sarah	CLARKE	ESC 2018-2020 Board – Chairperson Media Committee
Prof	Ian	GRAHAM	ESC 2018-2020 Board – Chairperson Statute Revision Taskforce
Mrs	Isabel	BARDINET	ESC Chief Executive Officer
Prof	Martin	COWIE	Chair ESC Digital Health Committee - CRT Nucleus member
Prof	Gerhard	HINDRICKS	CRT Nucleus member
Prof	Maddalena	LETTINO	CRT Nucleus member
Ms	Elisabetta	ZANNON	ESC Director Advocacy

CRT INDUSTRY MEMBERS MARCH 2020

Abbott	Dr	Philip B.	ADAMSON	Divisional Vice President and Chief Medical Officer – Heart Failure Division
Alnylam	Dr	Ilia	ANTONINO	Global Head of Medical Communications
Amgen	Mr	David	DELLAMONICA	
Amgen	Dr	Isabelle	LORDEREAU RICHARD	Executive Medical Director, Europe Medical Lead General Medicine Franchise – CRT Industry co-chair
AstraZeneca	Prof	Anders	HIMMELMANN	Senior Research Physician – Clinical Development – Global Medicines Development CRT Nucleus member
AstraZeneca	Dr	Karina	MORLEY	Global Head of External Scientific Engagement
Bayer AG	Ms	Pamela Elizabeth	COHEN	Scientific Initiatives
Bayer AG	Dr	Martin	van EICKELS	Head of MA Therapeutic Areas
Boehringer Ingelheim	Dr	Matias	NORDABY	Senior Corporate Medical Advisor
Bristol-Myers Squibb	Dr	Victoria	LEE	VP Worldwide Cardiovascular
Daiichi-Sankyo	Dr	Rodney	SMITH	VP Medical Affairs Head for Daiichi-Sankyo Europe
Daiichi-Sankyo	Dr	Mathias	LAMPARTER	
Edwards LifeSciences	Prof.	Martin	THOENES	Director Medical Affairs & Professional Education - Transcatheter Heart Valves – EMEA CRT Nucleus member
GE Healthcare	Ms	Lea Ann	DANTIN	Global Cardiology Strategist
GE Healthcare	Dr	Mathias	GOYEN	Chief Medical Officer Europe
GE Healthcare	Mr	Al	LOJEWSKI	Global General Manager Cardiology Care Area
Medtronic	Dr	Alphons	VINCENT	Director Medical Programs and Education - Cardiac Rhythm and Heart Failure CRT Nucleus member
Medtronic	Ms	Julie	FOSTER	VP Cardiovascular Group
MSD	Dr	Andrew	DAVIS	
MSD	Dr	Claudia	KAISER-ALBERS	Regional Clinical Director, Cardiovascular European Clinical Development
Novartis Pharma	Dr	Philippe	FERBER	Global Brand Medical Director Heart Failure

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Novartis Pharma	Dr	Heike	SCHWENDE	Worldwide Medical Affairs Director Heart Failure
Novartis Pharma	Dr	David	SOERGEL	Global Head, Cardiovascular, Renal & Metabolism Development
Novartis Pharma	Dr	Mathieu	WEITBRUCH	Regulatory Affairs
Novo Nordisk	Mr	Lars Hagen	JENSEN	Global Product Manager - Victoza Brand Team
Novo Nordisk	Dr	Florian M.M.	BAERES	Senior Global Medical Director - Global Medical Affairs - Liraglutide Diabetes
Pfizer	Dr	Nilo	CATER	Senior Global Medical Director CV/Metabolic Medical Affairs
Pfizer	Dr	Brian	KLEE	Global Medical Director
Pfizer	Dr	Fady	NTANIOS	Senior Director/Team Leader - Global Medical Affairs
Pfizer	Dr	Anthony	CHAN	Global Medical Director
Philips		Alexandra	GONCALVES	Sr. Medical Director - Global Cardiology Ultrasound
Roche Diagnostics	Dr	André	ZIEGLER	Clinical Science Leader - Cardiovascular Diseases – CRT Nucleus member
Sanofi	Dr	Gregory	MACARAEG	Senior Medical Director Global Scientific Relations and Medical Education PRALUENT and Early CV Compounds Global Medical Affairs Diabetes & Cardiovascular Business Unit
Sanofi	Ms	Sylwia	STASZAK	Head of Global Cardiovascular Public Affairs, Global Public Affairs DCV
Servier International		Tamara	KRCMAR	Medical communication Lead - Cardiology
Siemens AG	Dr	Friedrich	FUCHS	Strategy - Medical Office - Clinical Strategy -
Siemens AG	Ms	Petra	SCHLICHTNER	Advanced Therapies - Cardiology - Cardiology Solutions
Vifor Pharma	Dr	Thierry	SCHULMANN	Global Medical Lead Nephrology
Vifor Pharma	Dr	Fabio	DORIGOTTI	Global Medical Lead - Ferinject/Maltofer/Veltassa - Vice President