EHRA Scientific Documents policy

Content

1. EHRA scientific document categories (official documents of the EHRA) – figure 1

1.1 Expert Consensus Statement (ESC category: Clinical Consensus Statement)

Provides guidance for clinical management on topics not covered or not covered in sufficient detail in existing or upcoming ESC Clinical Practice Guidelines by evaluating scientific evidence or exploring expert consensus in a structured way.
This type of document is developed once per year in partnership and is a joint agreement between EHRA and three continental non-European societies (HRS, APHRS and LAHRS) with equal approval weight for the final document. The joint document is led by EHRA every 3rd year (table 1 attachment. rotation table). It is presented during the annual conference of the leading society or association and is published simultaneously in the official journals of each EP societies/association. If EHRA led, the method to develop the Expert Consensus Statement will follow the general rules for Clinical Consensus Statements.

The development of the expert consensus statement includes

- Copyright and use of the document
- Selection of Writing Chair and Co-Chairs
- Selection of Writing group/Committee members
- Staffing for the Document
- Meeting Agendas and Document and Supplementary Material Drafts
- Peer Review
- Consensus and Voting
- Approval Process/Endorsement
- Timelines
- Publication
- Length of the Document
- Updating the Document
- Costs

This type of document requires a derogation and well-defined exceptions to the general rules of the ESC scientific documents policy. A contract is required for the expert consensus statements, signed by all involved societies, including the ESC.

1.2 Clinical Consensus Statement (ESC category: Clinical Consensus Statement)

Provide guidance for clinical management on topics not covered or not covered in sufficient detail in existing or upcoming ESC Clinical Practice Guidelines by evaluating scientific evidence or exploring expert consensus in a structured way.

A Clinical Consensus Statement will include tables of advice based on available evidence and expert opinion, including voting.
For Clinical consensus statements that cover very technical and interventional topics, different solutions (including different devices, manufactures, workflows) may exist that usually have not been directly compared. For these practical guidance documents a list of *key points*, but without a table of advice may be used. For all Clinical Consensus Statements, the same definitions for strong consensus

and consensus should be applied and should be reached by at least one face-to-face meeting (during EHRA or ESC congresses) or online meeting.

It should be emphasized that an EHRA clinical consensus statement is not intended as a guideline. Only rarely will advice given in a clinical consensus statement be supported by the strongest level of evidence as provided by well-conducted, large randomised controlled trials and meta-analyses hereof. Evidence from observational studies often will have to be considered the most robust evidence available within selected areas included in such documents. Neither single observational studies nor meta-analyses of observational studies will allow causal conclusions to support advice. However, high quality observational studies can be considered as valuable supporting published evidence. In contrast, randomized, non-randomized, observational or registry studies with significant limitations of design or execution, case series, meta-analyses of such studies, physiological or mechanistic studies in human subjects should not be considered high quality supporting published evidence. For all documents the methodology of the conducted search strategy for the published evidence should be provided.
When considered helpful for the daily clinical practise, a Key Message (KM) can be developed. The Key messages contain the main messages of the published scientific documents in a concise format and providing highlights in an accessible format. Key messages should ideally be produced in parallel with the final stage of the document. The development of key messages should be initiated by the Document Chair and approved by the the EHRA Scientific Documents committee (EHRA Sc Doc) and EHRA Executive Board. Key messages are printed and published online, available in the EHRA KM app.

Further information can be found here: https://www.escardio.org/Guidelines/Scientific-Documents/EHRA-Key-Messages-App

An envelope is available for the development of KM (allocated budget decided upon when building the annual EHRA budget).

Table of advice and areas of uncertainty

Advice should be restricted to clinically relevant statements supported by published literature and/or expert consensus. The definitions of categories of advice and areas of uncertainty are provided in table 1.

Areas of uncertainty can be presented either in a table or as bulleted list. These topics are recognized by the expert group as highly relevant and important to be addressed by future trials/studies.

Strength of supportive evidence

The supportive evidence for the advice can be based on high quality published data or expert opinion (table 2). For each advice under the category “published data” the supporting RCTs, meta-analysis of RCT's or high quality and large observational studies needs to be summarized in a table of evidence (provided as supplementary material), applying the methodology and template as proposed by the ESC. The definition of “quality of data” should be in line with the definition provided by the ESC (reference will be added if the paper is published). Randomized, non-randomized, observational or registry studies with significant limitations of design or execution, case series, meta-analyses of such studies, physiological or mechanistic studies in human subjects do not necessarily need to be summarized in tables of evidence and are not considered high quality supporting

evidence, but are taking into consideration under the category expert opinion. A template for a table of evidence is provided supplementary table 2.

Reaching consensus and voting

Whenever advice is provided, the methodology used to achieve consensus should be reported in the introduction/method section of the clinical consensus statement. The writing process should at least include a face-to-face or online meeting between the authors to discuss and agree on each advice and on each statement listed in the table or bullet list of areas of uncertainty. Additionally, voting must be done for all advice (voting categories: Yes, no, abstain, if no/abstain, why). For expert opinion the categories strong consensus and consensus are defined as follows.

- Strong consensus: ≥90% of the WG agreed.
- Consensus: ≥70% of the WG agreed.

Table 1: Definition of categories of advice and areas of uncertainty

Definition	Categories of Advice
Evidence or general agreement that a given measure is clinically useful and appropriate	Advice TO DO
Evidence or general agreement that a given measure can be clinically useful and appropriate	Can be appropriate TO DO
Evidence or general agreement that a given measure is not appropriate or harmful	Advice NOT TO DO
No advice can be given because of lack of data or inconsistency of data. The topic is important to be addressed	Areas of uncertainty

Table 2: Categories and strength of supporting evidence

Types of supporting evidence:	Criteria	Strength of evidence
Published data[$]	>1 high quality RCT Meta-analysis of high quality RCT	 **META**
	High quality RCT >1 moderate quality RCT Meta-analysis of moderate quality RCT	 **RCT**
	High quality, observational studies	 **OBS**
Expert opinion[*#]	Strong consensus > 90% of WG supports advice	 **OPN**
	Consensus >70% of WG supports advice	 **OPN**

$ The reference for the published data that fulfil the criteria is indicated in the table of advice
*Expert opinion takes also into account: Randomized, nonrandomized, observational or registry studies with limitations of design or execution, case series, meta-analyses of such studies, physiological or mechanistic studies in human subjects
For areas of uncertainty: Strong consensus/consensus that the topic is relevant and important to be addressed by future trials.

Wordcount and layout

Recommended word counts no more than 12000-15 000 without references, no maximum numbers of table/figures. No maximum number of references but, prioritize references not older than 5 years.

Graphical abstract required. Table of advice or key points required.

1.3 Scientific statement (ESC category: Scientific Statement)

Interpret scientific evidence and provide a summary position on the topic without specific advice for clinical practice. A systematic search and review of scientific evidence is followed by a summary position of the EHRA. For the summary position, the same definitions for strong consensus and consensus should be applied and can be reached by a face-to-face meeting (during EHRA or ESC congresses), online meeting or email correspondence.

On top of the usual review and approval process applied to all scientific documents, the summary position needs to be approved by the EHRA Sc DoC and the EHRA Executive Board.

Wordcount and layout

Recommended wordcount no more than 8 000-10 000 without references, no maximum numbers of table/figures. No maximum number of references but, prioritize references not older than 5 years. EHRA summary position required.

1.4 Statement (ESC category: Statement)

Outlines and conveys the organisation's position or policy on medical and non-medical issues such as education, advocacy and ethical considerations. On top of the usual review and approval process, a statement needs to be approved by the EHRA Sc Doc and the EHRA Executive Board before publication.

Wordcount and layout

Recommended wordcount depends on the topic. In general, no more than 8 000-10 000 without references, no maximum numbers of table/figures.

2. Nonofficial documents of the EHRA

2.1 Viewpoints

The development of *viewpoints* is facilitated by EHRA and includes the following steps.
EHRA recognises the importance of the topic.
EHRA identifies independent and internationally recognized experts, who serve as Chair and Writing Group member and who need to disclose their conflict of interests according to EHRA4's rules. EHRA reviews the document and indicates statements that are in potential conflict with the association viewpoint. The official peer-review process is carried out by the editorial board of EP Europace.
EHRA will not appear in the title of the document and the document will not include any summary position from EHRA.
Recommended maximum word count 5000 words without references.

3. General information on the EHRA Scientific Documents policy (in agreement with the ESC Scientific Documents policy for clinical consensus statements, scientific statements and statements

Scientific Documents provide highly valuable advice for clinical management and interpretation of scientific evidence in areas not covered by ESC Clinical Practice Guidelines. While their topics and scope should not overlap with those of ESC Clinical Practice Guidelines, scientific documents may complement ESC Clinical Practice Guidelines by providing more in- depth information in specific areas that cannot be expanded in ESC Clinical Practice Guidelines. Heart rhythm management

includes rapidly evolving interventional techniques, which require very practical guidance which cannot be covered by ESC Clinical Practice Guidelines.

3.1 Partnership, Collaboration and endorsement

EHRA aims to involve external societies and internal entities (ESC family) whenever appropriate. Should the topic benefit from the involvement of other ESC specialty groups to ensure coordination of messages, the ESC SDoC also may suggest the inclusion of other groups/group representatives to join the writing group but may not mandate the inclusion of a specific author. EHRA may also be approached by internal or external entities to collaborate. See also ESC Scientific documents policy

There are three tiers of document involvement of *external* entities/societies:
Partnership (see 1.1): A joint agreement between two or more societies with equal approval weight for the final document.
Collaboration: Collaborating societies appoint at least one writing member and at least one reviewer, but with final approval granted by the lead society.
Endorsement: EHRA may seek endorsement from other societies that have neither joined in partnership nor collaboration. They do not conduct peer review or suggest changes.

3.2 EHRA led documents in collaboration with internal (ESC family) or external entities

- The involvement of internal and/or external entities needs to be approved by the EHRA Executive Board. The number of members from different entities to be involved in a document depends on the topic (27 authors max as per the ESC Sc. Doc policy) and will be proposed by the chairperson and approved by the EHRA SDoC.
- All entities need to nominate their official representative(s) in the writing group before submission of the proposal to the ESC SDoC.

- Pre-invitations to collaborate are sent out to the entities to nominate their representatives. EHRA can suggest authors, but the final decision lies with the internal or external entities. After approval by the ESC SDoC a memorandum of understanding needs to be signed in case of collaboration with sister societies and authors receive an official invitation with Author Agreement Form (AAF) to sign
- At least one reviewer per collaborating entity should be nominated and invited to participate in the blind review process. Sister societies are requested to appoint their representative(s). The list will be shared with the Review Coordinator.

3.3 Involvement of EHRA in documents led by other entities (ESC constituent bodies or external societies)

When EHRA is invited to collaborate on a document led by an ESC Association, Working group or Council, EHRA should have the capacity to designate at least two representatives— one to participate in the writing group and another to review the entire document. Failure to meet this condition could lead to EHRA declining the collaboration.

- Invitations to collaborate need to be sent to the EHRA Sc Doc.
- Collaboration needs to be approved by the EHRA Executive Board
- EHRA will appoint its representative(s) (author(s) and reviewer(s) for final approval of the document, the latter preferably a member of the EHRA Sc Doc.
- Internal entities need to get approval before the document proposal is submitted to the ESC SDoC.

3.4 Timelines (figure 2)

- EHRA scientific documents (excluded joint expert consensus documents) must follow a strict timeline pathway.
- The document has to be published no later than 18 months after the ESC Scientific Documents Committee approval.
- There is no extra budget for EHRA scientific documents (excluded joint expert consensus documents)
- In case timelines are not respected, a new scientific documents proposal form will have to be submitted and approved by ESC SDoC approval.
- The exact publication date will be confirmed by EHRA Executive Board and EP Europace Editor in Chief

4. Document development process (excluding Expert Consensus Statements (see 1.1)

4.1 Document proposal

A first proposal needs to be submitted to the EHRA Sc Doc via this link

Once reviewed and accepted the proposal will be submitted to the EHRA Executive Board for approval together with a proposal for a Chairperson**.** Once the proposal is approved the chairperson is responsible for finalising the ESC proposal form following the EHRA and ESC Scientific documents policy, respecting the criteria listed below. The expertise of each member of a writing group needs to be reported in the supplemental material.

- No more than 20 authors when the document is developed by EHRA. No more than 27 authors in case of collaboration.
- Inclusion of female authors aiming for numbers in line with the ESC Gender Policy.
- >50% EHRA members
- Representation of different geographies is required. Aiming for no more than 20% of authors from the same country, taking into account the number of available experts in the member country.
- A maximum of two authors from the same institution.
- Aiming for no more than 2 participations in an EHRA scientific document writing group within 4 years. Participation in more than 2 documents accepted if the personal expertise is indispensable for the document.
- Members of the EHRA Executive Board should be considered as Chairperson of a scientific statement or statement, only if their personal expertise is indispensable for the document, as they are also appointed as reviewers of these document categories.

- No conflict of interest according to the EHRA policy definition for writing group members

Chairperson and co-Chairperson selection

The chairpersons are selected based on his/her *internationally recognised expertise* in the field as documented through results of *PubMed searches*. In case of collaboration with other ESC association(s), ESC working groups or ESC committees on topics highly relevant for the members of these associations/WG/committees, a co-chairperson from these associations/WG/Committees can be proposed. This does not apply for collaboration with external entities, with the exception of Expert Consensus Statements. Co-chairpersons need to be recognised experts but do not need to be EHRA members. Internationally recognised expertise in a field requires:

- At least one recognised original publication as senior/leading author for the specific topic (original research)
- Additional scientific publications as senior/leading author (original research/reviews) in the area
- EHRA member
- No conflict of interest according to the EHRA policy definition for chairperson

Writing group members/ composition

Writing group members are selected based on their *internationally recognised expertise* in the field as documented through results of *PubMed searches*. EHRA members are preferred.

- For Clinical Consensus Statements, scientific statements**:** At least one scientific original publication as a senior/leading author for the assigned (sub)topic or in the area is required.
- In case of a Clinical Consensus Statement with a focus on practical guidance or a Scientific Statement with limited published evidence, it is required to be a clinical expert in the field with *significant personal experience.*
- The proposal submitter if a scientific or clinical expert

Additional writing group members

- A document coordinator (highly recommended): young (<40 years), interest in scientific work (e.g. publication as junior author, abstract presenter at EHRA)
- Patient representative (optional, dependent on topic)

Before submitting to the ESC SDoC

- Chairperson (co-chairs) has/have been approved by the EHRA Sc Doc Chairs and the EHRA Executive Board with a two thirds majority (≥5/7).
- Writing group has been approved by the scientific document chairs and the EHRA Executive Board, pre-invited and confirmed - preliminary author agreement.
- Collaborating entities have been approached, collaboration has been confirmed and co-authors nominated and confirmed.
- Preliminary/aimed publication date (e.g. at EHRA, ESC congress) has been confirmed with EHRA Executive Board.

After ESC SDoC approval (Max. 11 months until final manuscript)

- Official invitation letter author agreement form (AAF) sent by ESC ScDoc submission and approval of declaration of interest via the ESC.
- After ESC SDoc approval has been sent, no more changes can be made to the Writing Group.
- Approved proposal to be sent to Editor in Chief EP Europace for publication planning

4.2. Writing phase

- Declaration of Interest (DOI) campaign: all writing group members must have filled in their DOI before launching writing process.
- Kick-off meeting/call and assignment of tasks within the Writing Group, including one Chairperson and one member of the EHRA SDoC. This member will support and advise the Writing Group throughout the writing, review and submission phase.
- Review of literature, writing process and finalizing of draft for internal review.
- Internal review, face-to-face (during EHRA/ESC congresses) or online meeting, voting.

4.3. External Review, review coordinator and reviewers

For all document types, the below review process and rules apply (except for Joint Expert Consensus Statements)

- The external review process is under the auspices of the EHRA SDoC.
- The review coordinator(s) is selected based on his/her internationally recognised expertise in the field as documented through results of PubMed searches or a recognized clinical expert in the field.
- The review coordinator has no conflict of interest according to the EHRA policy definition for review coordinators
- Whenever appropriate a member of the EHRA SDoC will be appointed as review co-ordinator.
- A minimum of 6 reviewers need to be appointed (including coordinator).
- The review process will be handled in a blind manner: Implementing a double-blind review process where the reviewers and authors are not aware of each other's identities to ensure impartial evaluations.
- >50% of reviewers should be EHRA members.
- In case of collaborating entities at least one reviewer per entity should be nominated and invited. Sister societies are requested to appoint their representative(s).
- All reviewers will undergo the same DOI process as the writing group members.
- In case of scientific statements, the document will be also reviewed by the Executive Board for potential conflicts with the EHRA policy.

For Statements

- At least two members of the Executive Board should be nominated as reviewers.

4.4. ESC Scientific Documents approval on final document and publication process

ESC Scientific Documents approval

- Once ready the document is submitted to the ESC Scientific Documents team (for the ESC ScDoC) by the EHRA Team.

Publication process

- The final document is sent to the Editor-in-Chief by the EHRA Team.
- Once published the lead author will have to inform the EHRA team so that the document can be promoted on the ESC/EHRA webpages and via the regular communication channels (bulletin/newsletter) and social media when appropriate.

4.5. Job descriptions

Chairpersons

- Conception and design of proposal form and an online meeting with chairs of SDoC for
  (1) Table of content
  (2) Propose involvement of ESC associations/WG/committee and sister societies
  (3) Propose document coordinator and writing group members.
- Completes Author Agreement Form (AAF), as per the DOI policy.
- Responsible for the completion of the DOI process, as per the ESC DOI policy.
- Coordination with Co-authors: kick off meeting, section allocation.
- Follow up of the document's progression in order to ensure timely submission.
- Citation management.
- Supervises the internal review process.
- Revises and responds to external reviewers and provides information to co-authors.
- Corresponds with ESC SC doc and then Editors of target publication Journal.
- Approves of the Final Version.
- Acknowledges Contributions: determining the order of authorship.
- Checks with co-authors their names and affiliations are correct (double check required when receives the proofs from the editor)
- Communicates to EHRA team once the document is published.
- Develops/Supervises the development of Key messages if applies and if relevant.

Writing group members

- Complete DOI and Author Agreement Form (AAF), as per the DOI policy.
- Attend kick off meeting and other online meetings.
- Review published evidence.
- Propose advice with supporting evidence in table format.
- Writing, Editing and deliver in the requested timelines.
- Peer Review.
- Provide approval on the draft manuscript before external review and on final manuscript before publication
- Responsible for providing their affiliations and checking they are up to date at time of publication

Document coordinator

- Supports the Chairpersons in coordinating the document and ensures timelines are respected
- Responsible for the Citation management
- Checks with co-authors their names and affiliations are correct (double check required when receives the proofs from the editor)
- Communicates with the EHRA team at each milestone
- Responsible for coordinating copyright requests (permission to use certain figures from previous publications)
- Responsible for submitting the final document to the journal for publication

Review coordinator

- Identifies Reviewers.
- Coordinate Reviews.
- Ensures objectivity and impartiality.
- Completes Confidentiality Form (CF)/Author Agreement Form (AAF), as per the DOI policy.
- Is responsible for the DOI completion process as per the ESC DOI policy.

- Ensures Quality Control:

(1) Ensures Rigor: Verifying that the feedback provided by reviewers is constructive, relevant, and aligns with the standards of the publication.
(2) Addresses and resolves any discrepancies or conflicts in reviewer comments.

- If a conflict exists between the authors' position and the reviewers, and is not resolved after the second round of reviews, a call will be organised between the EHRA Executive Board and the EHRA Scientific Documents committee Chairpersons to take the final decision.

Reviewer

- Reviews in a timely manner.
- Ensures objectivity and impartiality.
- Completes DOI and Confidentiality Form (CF)/Author Agreement Form (AAF), as per the DOI policy.

7. Attachment

Table 1: Rotation table

Current Rotation	EHRA Proposed
2023 – HRS Led	2023 – HRS Led
2024 – APHRS Led	**2024 – EHRA Led**
2025 – EHRA Led	**2025 – APHRS Led**
2026 – HRS Lead	2026 – HRS Lead
2027 – APHRS Led	2027 – APHRS Led
2028 – EHRA Led	2028 – EHRA Led
2029 – HRS Led	2029 – HRS Led

Table 2: Table of evidence- modified ESC template

Table of advice	Title of the table									
Literature search strategy	Keywords									
META-ANALYSES OF RANDOMIZED CONTROLLED TRIALS										
Study first author surname and year + acronym (please sort by date of publication in descending order)	PMID and endnote reference for study	Population	Number of patients	Intervention and control	Key inclusion & exclusion criteria	**Type of analysis** (random-effect, fixed-effect, Bayesian approach)	Relevant outcome(s)	PROMs reported	Other methodological aspects (small-study effect, large unexplained heterogeneity, publication bias, quality of individual studies)	Key findings and WG interpretation
RANDOMISED CONTROLLED TRIALS										
Study first author surname and year and acronym (please sort by date of publication, descending)	PMID and endnote reference for study	Population	Number of patients	Intervention and control	Key inclusion & exclusion criteria	**Type of analysis** (Intention-to-treat (ITT), per-protocol (PP), ITT or per-protocol with adjustment for pre-specified covariates)	Relevant outcome(s)	PROMs reported	**Other methodological aspects** (allocation concealment, single/double blinding, sham procedure in device trials, missing data on outcomes,	Key findings and TF interpretation

									outcome central adjudication…)	
NON-RANDOMISED STUDIES										
Study first author surname and year and acronym (please sort by study type, then date, descending)	PMID and endnote reference for study	**Population and study type** (meta-analysis of non-RCT, case-control, cohort, etc.)	Number of patients	Intervention and control	Key inclusion & exclusion criteria	**Type of analysis** (covariate adjustment, propensity score matching/weighting/adjustment, trial emulation, quasi-experimental design…)	Relevant outcome(s)	PROMs reported	Other methodological aspects Bias in design (i.e., immortal-time bias, survivorship bias etc.), risk of residual confounding (i.e., e-value, falsification endpoint), other issues as evaluated in specific tools (i.e., ROBIN I), generazibility.	Key findings and TF interpretation

Figure 1: EHRA documents

Documents Type (from EHRA perspective)	Scientific document EHRA (sub-category)	Official name from Scientific document ESC policy	Table of advice	EP Europace publication	Co-publication	Developed by	Contract	Chair	Co-chair	Review under the auspices of EHRA SDoC	Budget
Clinical consensus Statement	Expert Consensus Statement	Clinical consensus Statement	Yes	Yes	Yes	Joint document Mandatory: EHRA, HRS, APHRS, LAHRS	Yes	Yes	Yes	Review coordinator/ External reviewers	Yes
	Clinical Consensus Statement		Yes	Yes	No Optional for selected documents	EHRA Optional collaboration with: Associations WG, ESC committees European association Sister Societies	Associations Working groups ESC committees Other European association: NO Sister Societies: Memorandum of Understanding	Yes	Optional for ESC associations /WG/ Committees	Review coordinator/ External reviewers	No
	A Clinical Consensus statement "Practical guide"		No advice Key points/ messages								
Scientific statement	Scientific Statement	Scientific Statement	No advice EHRA summary position	Yes	No Optional for selected documents	EHRA Optional collaboration with: Associations WG, ESC committees European association Sister Societies	Associations Working groups ESC committees Other European association - NO Sister Societies: Memorandum of Understanding	Yes	Optional for ESC associations /WG/ Committees	Review coordinator/ External reviewers	No
Statement	Statement	Statement	No	Yes	No	EHRA	No	Yes	Optional	SDoC chairs Executive board External reviewers	No
Viewpoints	No	No	No	If accepted after peer-review	No	Independent expert (identified by EHRA Sc Doc)	No	Yes		SDoC Peer-review EP EUROPACE	Yes

Figure 2: Timelines