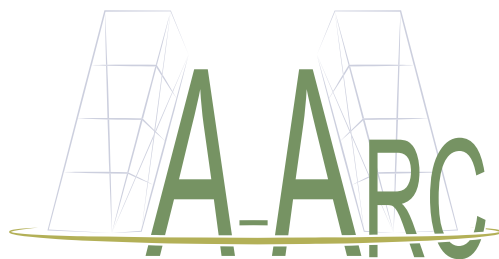


Adherence - Academic Research Consortium (A-ARC): Focus on Antiplatelet therapy



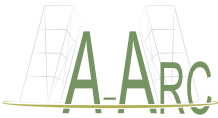
Eurostars Madrid Tower Hotel

MADRID SPAIN

19-20
JUNE **2015**

CARDIOALYSIS
Clinical Trial Management - Core Laboratories

fostering
discoveries



ADHERENCE-ACADEMIC RESEARCH CONSORTIUM (A-ARC): FOCUS ON ANTIPLATELET THERAPY

SCOPE

- Critical appraisal of methods employed in previous major antiplatelet studies on how duration of and adherence to therapy have been collected for coronary artery disease patients (see appendix A).
- To define a consensus nomenclature to standardize reporting of antiplatelet therapy status in trials that could be applied to other cardiology medications.
- To inform the community and major stakeholders on the most suitable methodologies to design, conduct and analyze antiplatelet therapy adherence in clinical studies. This methodology could be also applied to other cardiology medications

ARC BOARD

The ARC steering group comprises appointees from each of the 4 founding research organizations in conjunction with advisory liaison representation from the U.S. FDA (please refer to the ARC charter attached).

The A-ARC initiative will consist on three separate but complementary modules.

NOMENCLATURE

Relevant stakeholders will be invited ahead of the meeting to participate in a survey whereby key information on how adherence has been collected and analyzed in previous major antiplatelet studies in order to inform the nomenclature workshop.

DESIGN

Experts in the field will be invited to critically appraise strengths and limitations for all study formats/designs so far conducted, including target patient population, timing of randomization, relevant study endpoints and ultimately to provide proposals for study designs suited to address gaps in knowledge and possibly inform practice. This document will then be distributed for comments among all participants.

09:00 - 12:00	Arrival and Registration Coordinators Gerrit-Anne van Es (<i>ARC</i>) - Hector M. García-García (<i>Cardialysis</i>)
13:00-13:15	The ARC Enterprise: where are we coming from and where are we heading to Patrick W. Serruys
13:20 - 13:30	Why are we here? What can we achieve together? Marco Valgimigli
	MEDICATION ADHERENCE Coordinator Gregg Stone
13:30 - 13:40	Lessons from an adjacent field (risk stratification and adherence) Gregory Lip ^{Disco} webex
13:40 - 13:45	Discussion
13:45 - 13:55	Case example : ROCKET AF trial Pierluigi Tricoci
13:55 - 14:00	Discussion
14:00 - 14:10	Case example: PARIS registry Roxana Mehran
14:10 - 14:15	Discussion
14:15 - 14:25	Taxonomy and measurements Bernard Vrijens
14:25 - 14:35	Consequences and interventions Bernard Vrijens
14:35 - 15:00	Discussion
15:00 - 15:30	BREAK

NOMENCLATURE**Coordinators** | Bernard Vrijens - Pascal Vranckx

15:30 - 15:40

Survey results
Francesco Costa

15:40 - 15:50

Discussion

15:50 - 16:05

Proposed nomenclature
Hector M. García-García

16:05 - 16:20

Panel discussion: Proposed nomenclature

16:20 - 17:20

NOMENCLATURE WORKSHOPS**Coordinators** | **W1:** Patrick Serruys - Roxana Mehran
| **W2:** Dominique Angiolillo - Giles Montalescot- Pros- and Cons- of proposed nomenclature
- Suggested adaptations

17:20 - 18:20

Panel discussion
Coordinators | Bernard Vrijens - Pascal Vranckx

18:20 - 18:40

Closing remarks of Day 1
Marco Valgimigli
(All participants)

09:00 - 09:10	Agreed nomenclature: Any second thoughts? Gabriel Steg, Bernard Vrijens, Pascal Vranckx and Marco Valgimigli
09:10 - 09:20	Panel discussion
09:20 - 09:35	CAPTURING ADHERENCE CRF prototype Coordinators Usman Baber - Ana Guimarães
09:35 - 10:35	CRF WORKSHOPS Coordinators Pierluigi Tricoci - Gregg Stone - Pros- and Cons- of proposed CRF items - Suggested adaptations
10:35 - 10:45	Panel discussion: CRF adherence block
10:45 - 11:15	BREAK
11:15 - 11:25	Agreed CRF adherence block Ana Guimarães - Usman Baber
11:25 - 11:45	DESIGN AND ANALYSIS Coordinators Jan Tijssen - Peter Juni - Karen Pieper - Usman Baber Panelists Antonio Colombo, Fausto Feres, Gabriel Steg, Gregg Stone, regulatory participants, industry medical and statistical teams
11:45 - 12:00	Analysing and reporting adherence: issues & potential solutions Karen Pieper - Jan Tijssen
12:00 - 13:30	Discussion
12:00 - 13:30	LUNCH BREAK

DESIGN AND ANALYSIS (cont.)**Coordinators** | Jan Tijssen - Peter Juni - Karen Pieper - Usman Baber**Panelists** | Antonio Colombo, Fausto Feres, Gabriel Steg, Gregg Stone, regulatory participants, industry medical and statistical teams

13:30 - 16:00

DESIGN WORKSHOP THEMES**(case examples):**

1. Superiority design for efficacy & safety outcomes
2. Non-inferiority design for efficacy & safety
3. Hierarchical testing
4. Registries

16:00 - 16:30

Proposed solutions and general recommendations on statistical analysis

Jan Tijssen - Peter Juni - Karen Pieper - Usman Baber

16:30 - 17:00

Closing remarks of Day 2

Jan Tijssen

17:00 - 17:15

Meeting adjourn: next steps (i.e. writing group)

Marco Valgimigli - Gerrit- Anne vas Es

17:15 - 18:00

DEPARTURES

APPENDIX A

List of major antiplatelet therapy studies in coronary artery disease:

ARCTIC	ITALICS	ROCKET-AF
CHARISMA	OPTIMIZE	SECURITY
CURE	PRODIGY	TRACER
DAPT	PARIS	TRA-2P
DES LATE	PEGASUS	TRITON
EXCELLENT	PLATO	TRILOGY
ISAR SAFE	RESET	ZEUS

CONFERENCE VENUE / HOTEL

EUROSTARS MADRID TOWER HOTEL

Paseo de la Castellana, 259 B, 28046 Madrid

APPOINTED MEETING ROOM

PEKIN ROOM

SCIENTIFIC PRESENTATIONS

The Meeting rooms will be equipped with Screen, Data Video Projector for Microsoft Power Point presentations, Note pads, pens and laser pointers.

TRANSFER SERVICES FROM/ TO AIRPORT

Transfer services will be available from/to **Adolfo Suárez Madrid-Barajas Airport**, according to your flight itinerary. Please note that the pick-up time regarding your departures will be 2hrs prior your flights.

MEETING SECRETARIAT & OFFICIAL TRAVEL AGENCY

The Meeting's Secretariat will operate during meeting hours.



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