CORCYM Guidelines for the Publication of Results from CORCYM Sponsored Clinical Investigations and CORCYM Funded Research

Definitions:

CORCYM-Sponsored Clinical Investigation:
Clinical Investigations in which CORCYM is the sponsor, "taking responsibility and liability for the initiation and management of a clinical investigation and arranging the financial set-up" (ISO14155:2020).
CORCYM Funded Research (Investigator Initiated Research (IIR))
Clinical Investigations designed, developed and managed by an independent investigator(s) or academic institution taking on the responsibility and liability of a sponsor as defined by the ISO14155:2020. An IRR Sponsor may request funding from CORCYM in form of financial and/or scientific support.

Introduction

CORCYM is dedicated to offering innovative solutions aimed at improving patients' lives. Our expertise in the development of heart valve prostheses and repair devices provides our users with technologically advanced platforms backed by solid clinical evidence. We continuously strive to discover and develop our products further for patients around the world. We conduct clinical studies in an ethical and rigorously scientific manner, collaborating with leading experts in the field, to clearly demonstrate the benefits, risks and value of our products to physicians and to the patients who receive them. We accept the obligation to facilitate publication of medically important clinical data in a timely, objective, accurate and balanced manner. At the same time, CORCYM has an obligation to protect its proprietary information and its intellectual property. These considerations do not in any way affect our longstanding practice of making information public that relates to the efficacy and safety of our products by physicians and patients.

CORCYM retains the intellectual property rights for all data from CORCYM-Sponsored Clinical Investigations and, as such, will make the final decision on the release of data.

Applicability and References

These guidelines apply to the publication of results from CORCYM Sponsored Clinical Investigations involving a company product, including IIRs, if any support is provided by CORCYM. These guidelines apply to all instances in which CORCYM data are to be published or shared with external stakeholders. CORCYM aims to ensure ethical, accurate, complete and transparent reporting of study results and supports widely recognized industry standards for publications[1].

CORCYM retains the right to review all articles referring to data generated from sponsored Clinical Investigations as well as IIRs.

Authorship

Potential authors must meet all four criteria laid down by the ICMJE:
https://www.icmje.org/recommendations/

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and

resolved. In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors

All authors, both internal and external to CORCYM, should disclose all potential competing interests to targeted journals at the time of the initial manuscript submission and of poster and podium presentations, with the level of detail determined by these entities. Disclosures should include, but are not limited to, employment, funding for research and/or promotional activities and ownership of stock or stock options.

CORCYM will not pay potential authors for their time in conducting data analysis, writing or reviewing the paper.

The decision on who will be first author will be made prior to starting to write the papers and ideally prior to any study analyses being performed.

The first author should meet all four criteria listed above and should not hold additional responsibilities responsibility (e.g., member of Data Monitoring Board [DMB], for the Clinical Investigations. Additional criteria for first authorship may include high rate of recruitment into the study, timely and accurate recording of patient data into the Electronic Data Capture System (EDC), and no major or critical audit findings at the study site. The first author should make a significant contribution to writing and reviewing the paper. Additional criteria for first authorship may be discussed and agreed by CORCYM. The same criteria will apply to second and third authors.

All clinical investigators and sites which have screened, or enrolled subjects will be acknowledged as contributors in the pivotal paper. Generally, those who have not enrolled a patient will not be considered as named authors or contributors.

All members of study expert committees (e.g Clinical Event Committee (CEC), DMB) will be acknowledged in the pivotal paper.

All members of the steering committee can be named as authors if all the criteria requested by the ICMJE as outlined above are met.

In line with the EMA's Guidance on the Role of Data Monitoring Committees (EMEA/CHMP/EWP/5872/03 Corr; 2005)[1], the chair and members of the Data Monitoring Committee (DMC) will not be named authors on any pivotal papers as this presents a conflict of interest, with the exception of any planned safety analyses and publications.

All named authors should be willing and able to present the data at any international or regional meetings, respond to questions on the study design and implementation and to defend the study, and any paper(s) originating from the study, in case of criticism.

CORCYM seeks to support the development of new investigators and researchers and will seek to provide opportunities for authorship to less experienced persons where possible if they meet all the required criteria.

Generally, no single investigator or researcher will be first author on more than one paper arising from CORCYM-Sponsored Clinical Investigations. The last author will also vary across the key papers.

Key Principles for Publications – CORCYM Sponsored Research

CORCYM is responsible for the publication strategy and planning, but will take into consideration suggestions from any of the investigators participating in CORCYM sponsored research or proposals from sites interested in funding for a subject of interest for the company.

The publication plan will be shared with and agreed by all Principal Investigators at the initiation of the study, if available, or prior to the planning of the first publication in a CORCYM sponsored Clinical Investigation. In any case, agreement is needed before any publication of clinical data is planned.

Depending on the nature of the proposal and/or publication suggestions, CORCYM will decide on which investigators meet the criteria above and should be offered authorship. Inclusion of one or more members from CORCYM may be considered, provided that the above-mentioned authorship criteria are met. The main authors and CORCYM will determine the target journal.

Multicenter Clinical Investigations are designed to take full account of data accumulated from all centers and therefore, CORCYM discourages presenting or publishing data gathered from a single or small group of centers, unless prior agreement by CORCYM has been granted. Center-specific analyses have greater variability and lead to exaggerated observed-treatment effects that are inherently less reliable. Valid conclusions regarding the primary endpoint of a Clinical Investigation can only be based on the analyses predefined by the protocol.

Individual case studies of subjects enrolled in CORCYM Sponsored Clinical Investigations in a single center or small group of centers will be considered on their merits. The decision to present at conferences or to publish case studies will be made between the principal investigator(s) of the site (or sites in case of small groups of centers) and CORCYM. Case studies will not be approved if their publication jeopardizes the overall analysis and publication of the Clinical Investigation.

CORCYM will provide administrative support to the corresponding author to ensure all necessary documentation is available for submission to the journal as required.

CORCYM will provide statistical and medical writing support for publications on CORCYM Sponsored Clinical Investigations.

CORCYM adheres to all rules to protect subject privacy and confidentiality.

Any editorial rules required by journals will be adhered to.

Key Principles for Publications – CORCYM Funded Research/IRR

Any request for IIRs should be submitted to CORCYM. A dedicated CORCYM internal Board will screen and approve/reject all the requests.

Publishing the results of IIRs is the responsibility of the Investigators, provided that below criteria are met.

All articles should be submitted to CORCYM for review at least 60 days prior to submission to the target journal and according to the contractually agreed terms and conditions following approval of the IIR, so that CORCYM can review the proposed publication carefully to protect its proprietary information and its intellectual property.

CORCYM may provide statistical and/or medical writing support for authors and will provide funding for such support as necessary. Such support will be publicly disclosed.

Data should be presented or published in a timely manner, although CORCYM reserves the right to delay publication or presentation in case of issues related to protecting the intellectual property rights, as detailed in the research agreement.

CORCYM adheres to all rules to protect subject privacy and confidentiality.

[1]**Industry Standards for Publications:**

- GPP3, 2015
  Good Publication Practice for Communicating Company-Sponsored Medical Research
- ICMJE Recommendations
  Recommendation for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals; by the International Committee of Medical Journal Editors
- EQUATOR Network
  Enhancing the QUAlity of Transparency Of health Research Reporting Guidelines
- AdvaMed Code
  Advanced Medical Technology Association (AdvaMed)
  Code of Ethics on Interactions with Health Care Professionals
- MedTech Europe Code
  MedTech Europe Code of Ethical Business Practice
- APACMed Code
  Asia Pacific Medical Technology Industry Association (APACMed) Code of Ethical Conduct for Interactions with Health Care Professionals
- MECOMED Code
  MECOMED Code of Ethical Business Practice
- EMA's Guidance on the Role of Data Monitoring
  (EMEA/CHMP/EWP/5872/03 Corr; 2005)