POLICY DISCLOSURE OF CLINICAL RESEARCH INFORMATION

OBJECTIVE
Actelion is committed to publicly disclosing information about clinical research in a timely manner as this information is important and critical to the medical profession, patients, and the public.

SCOPE AND APPLICABILITY
This policy addresses public disclosure of clinical research protocols and results via clinical trial registries and the scientific literature, as well as access to clinical research data.

This policy applies only to Actelion-sponsored clinical research. It does not apply to Investigator-Initiated Studies (IISs).

This policy applies to all Actelion employees, and as appropriate, to those parties with whom Actelion contracts (e.g., CROs, medical writing agencies or consultants) who are involved in the activities described in this policy.

REGISTRATION OF ONGOING CLINICAL RESEARCH ON PUBLICLY ACCESSIBLE, INTERNET-BASED REGISTERS
Actelion posts summary information of all ongoing Actelion-sponsored clinical trials of investigational and marketed medicines on Actelion’s own Clinical Trial Register (SMADAR: http://trials.actelion.com/) and on external/national registries, such as ClinicalTrials.gov (http://www.clinicaltrials.gov/) and other websites as required by law or requested by medical journals.

Actelion also posts summary information of ongoing prospective observational research on Actelion’s Clinical Trial Register and, as applicable, on external/national registries, such as ClinicalTrials.gov.

In all cases, disclosure will be undertaken in a manner consistent with applicable national laws and rules governing protection of intellectual property.

CONTENT
Actelion is committed to publically disclose information about clinical research in a timely manner as this information is often important and critical to the medical profession, patients, and the public.

PURPOSE
This policy reflects Actelion’s commitment to ethical, open, and transparent communication of information relating to Actelion-sponsored clinical research that evaluates Actelion’s investigational or marketed medicines, in line with country-specific legal requirements and international standards regarding public disclosure of clinical research.

SCOPE
This policy addresses public disclosure of clinical research protocols and results via clinical trial registries and the scientific literature, as well as access to clinical research data.

This policy applies only to Actelion-sponsored clinical research. It does not apply to Investigator-Initiated Studies (IISs).

This policy applies to all Actelion employees, and as appropriate, to those parties with whom Actelion contracts (e.g., CROs, medical writing agencies or consultants) who are involved in the activities described in this policy.

When Actelion has an alliance with another company for the development and/or marketing of a product, Actelion and the other company agree, in writing, as to which party has responsibility for all processes related to public disclosure of information relating to clinical research covered under the alliance; however, Actelion retains responsibility for public disclosure of clinical research information for all research sponsored by Actelion. This Policy applies to all such research sponsored by Actelion or for which Actelion has been vested with responsibility for management of the public disclosure of clinical research information.

REVIEW AND APPROVAL
Corporate Affairs and Compliance 01-Jul-13 signed 1 Clinical Development 05-Jul-13 signed 2 CEO 31-Jul-13 signed 3

1 Author, signs for correctness and completeness
2 (Only if applicable) Reviewer, signs for control of correctness and completeness
3 Approver, signs for the release of this document
REGISTRATION OF CLINICAL RESEARCH RESULTS ON PUBLICLY ACCESSIBLE, INTERNET-BASED REGISTERS

Results of Actelion-sponsored clinical research are publicly disclosed on Actelion’s Clinical Trial Register, and, as applicable, on external/national registries, such as ClinicalTrials.gov and other websites as required by law:

- **Post-approval trials:** Posting summary results of registered clinical trials with already marketed medicines within one year of the study completion date
- **Pre-approval trials:** Posting summary results of registered clinical trials with investigational medicines within 30 days of first marketing authorization approval for the new medicine
- **Terminated research programs:** Posting summary results of registered clinical trials within one year of the public announcement of the termination of development of the compound
- **Observational research:** Posting summary results of registered observational research within one year of the study completion date

In all cases disclosure will be undertaken in a manner consistent with applicable national laws and rules governing protection of intellectual property.

PUBLICATION IN SCIENTIFIC LITERATURE / MEETINGS

Whenever possible, public disclosure will also be via publication in the scientific literature, regardless of the outcome of the clinical research. Actelion supports the timely publication of the results of any Actelion-sponsored clinical research that has been registered on Actelion’s Clinical Trial Register and is of scientific or medical importance.

Actelion aims to have submitted manuscripts for publication (i) of registered clinical trials of investigational medicines within 12 months of first marketing authorization approval for the new medicine and (ii) of registered clinical trials of already approved medicines within 18 months of the completion of the trial.

Clinical trial investigators involved in multi-site trials are asked to agree with Actelion’s policy that any first publication will reflect the overall trial results.

Actelion reserves the right to review any manuscripts, presentations, abstracts or other public disclosures relating to Actelion-sponsored clinical research before they are submitted for publication or otherwise publicly disclosed by investigators. Actelion is committed to responding in a timely manner. Actelion does not suppress or veto publications or other appropriate public disclosures of clinical research results by investigators; however, in rare cases, it may be necessary to delay publication or other public disclosures for a short time to allow Actelion to seek intellectual property protection.

Clinical research results should be reported in an objective, accurate, balanced, and complete manner, with a discussion of the strengths and limitations of the research, as outlined in several guidance documents.

In the case of conflicts arising due to differing opinions or concerning data interpretation, Actelion will mediate and help resolve any and all issues through objective scientific discussion and with deference toward ensuring subject/patient welfare.

Actelion fully respects the privacy between subjects/patients and healthcare professionals and ensures that scientific publication will not breach subject/patient confidentiality.

Further details related to publications of Actelion-sponsored clinical research are described in the Actelion Policy for Scientific Publications.

UNIQUE IDENTIFIER

Actelion uses a unique trial identifier (e.g., company-assigned study ID) for website postings and in all subsequent publications of clinical research to enhance transparency.

ACCESS TO CLINICAL TRIAL DATA

In the case of collaboration between Actelion and third parties, a formal agreement will be drawn up to effectively secure intellectual property. This agreement will cover property ownership and data access.

Actelion will take responsibility to ensure that all Actelion-sponsored clinical trials are compiled in a complete database. Towards attaining regulatory approval, Actelion will make these databases available to the responsible regulatory agencies for all registration trials.

After conclusion of a clinical trial, Actelion will grant investigators, on request, the randomization code for their individual study subjects. All participating investigators of a multi-site clinical trial will be provided with a summary of the trial results. In addition, investigators who have participated in a multisite clinical trial will be able to review more extensive data displays for the entire trial in response to reasonable scientific inquiry.

Investigators who are authors of trial-related publications will be provided with the relevant documentation that is needed to support the planned publication. Access to clinical trial data by authors of a publication of an Actelion-sponsored trial is further addressed by the Actelion Policy for Scientific Publications.
**REFERENCES**

1. International Committee of Medical Journal Editors (ICMJE) Uniform requirements for manuscripts submitted to biomedical journals: Writing and editing for biomedical publication. (Updated October 2008)

**GLOSSARY**

**Actelion-sponsored** - Actelion acts as Sponsor and assumes all the responsibilities of a Sponsor.

**Actelion-supported** - Actelion supports financially and/or through the supply of drug, but does not act as Sponsor.

**Clinical research** - Clinical trials [phase I-IV] and other types of clinical research, such as prospective observational research.

**Clinical trial** - Any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or pharmacokinetic effects or properties of an investigational or marketed medicine(s), and/or to identify any adverse reactions to an investigational product(s), with the objective of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

**Investigational medicine** - A compound being investigated for therapeutic purposes and which has not yet been approved for commercialization. In the early phases of clinical research it will be referred to with its ACT-number and later with its INN-approved name.

**Investigator-initiated study** - A study which the investigator initiates and conducts and acts as the sponsor. The responsibilities include both those applicable to an investigator and a sponsor.

**Observational research** - Epidemiological study that does not involve any intervention, experimental or otherwise. Such a study may be one in which nature is allowed to take its course, with changes in one characteristic being studied in relation to other characteristics.

**Patient** - A subject, either healthy or having a disease, who is taking part in a clinical research study.

**Sponsor** - An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial and non-clinical research projects.