

YOU AND ADMERITOX

YOU are involved in preclinical development, scientific writing or regulatory submission concerning human or veterinary drugs. You are dealing with a particular issue and you are looking for the appropriate person(s) to team up with to find the solution.

ADMERITOX is a consultancy, dedicated to the following services:

- preclinical development strategy;
- operational support for preclinical study design, selection of Contract Research Organization and study monitoring;
- scientific writing of preclinical study reports, publications, position papers and documents for regulatory submission.

ADMERITOX is **Ria Vos PhD**



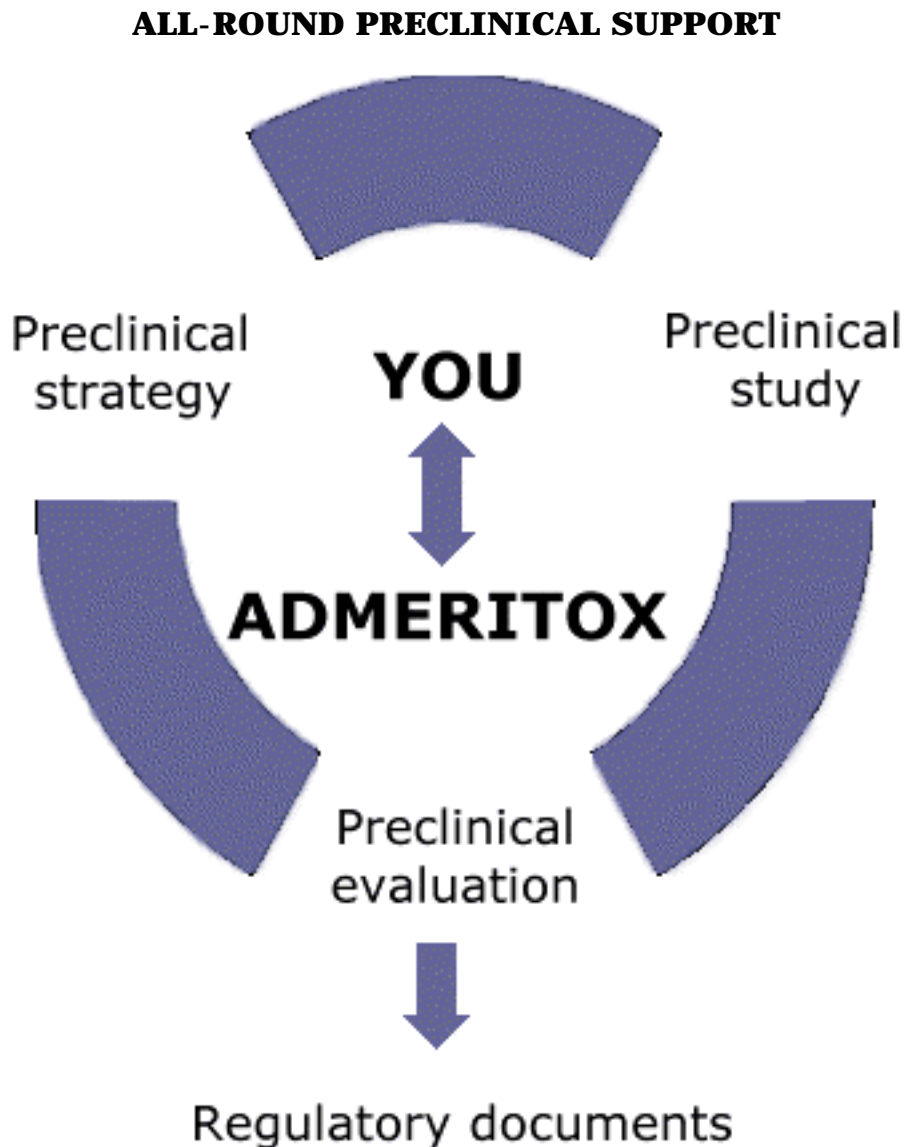
Ria Vos has more than 13 years of experience in preclinical development (ADME, safety pharmacology and toxicology) of pharmaceuticals. Her expertise includes virtually all aspects of preclinical development, ranging from the design of the preclinical program, to supervision, monitoring and reporting of the various preclinical studies, and the writing of the preclinical parts of regulatory documents such as the Common Technical Document.

After a PhD in Toxicology and Biochemistry (Agricultural University of Wageningen, The Netherlands), Ria Vos joined the pharmaceutical company Organon in The Netherlands. She was manager of the ADME group, study director of ADME studies and a member of various Development Project Teams for 7 years. She then became manager of the preclinical International Project Team Representatives, where she supervised the preparation and implementation of preclinical (ADME and

toxicological) development strategies, the safety evaluations prior to the start of "first" clinical studies, and the preclinical contributions to position papers and regulatory documents. After five years in that position, she moved to France for family reasons. She started working as a preclinical consultant early 2004.

Ria Vos has participated in preclinical programs for more than 40 projects, covering several therapeutic areas and routes of administration. In addition, she has had the opportunity to contribute to various meetings with the FDA and to international and multidisciplinary cooperations with a number of different pharmaceutical companies.

SERVICES



PRECLINICAL DEVELOPMENT STRATEGY

Preclinical studies (ADME, safety pharmacology and toxicology) are essential for the development of your product and the regulatory submission of your dossier. For each drug project, a well-conceived preclinical development strategy, focussed on your specific needs, is the indispensable basis of a first-time-right study program. A first-time-right approach results in the timely start of clinical development phases, efficient dossier preparation and an uneventful review by regulatory authorities.

By asking **ADMERITOX** to work out the preclinical development strategy for your drug project, **YOU** will get:

- a preclinical development strategy in compliance with your short-term and long-term project objectives and integrated with your chemical, pharmaceutical, clinical and regulatory strategies;
- a preclinical development strategy tailored to your existing data and the appropriate regulatory guidelines;
- a preclinical development strategy with a clear rationale and objectives for the studies envisaged;
- a preclinical development strategy allowing you to proceed to a satisfactory planning, an accurate budget and a successful control of the potential constraints.

PRECLINICAL OPERATIONAL SUPPORT

A preclinical study –irrespective of whether it is conducted by your organization or subcontracted- is an irrevocable building block of the dossier you will submit to regulatory authorities. Every study engaged under Good Laboratory Practices (GLP) and the data generated will need to be presented. It is therefore crucial to avoid ill-designed or ill-conducted studies as such studies will provide equivocal results and stretch development timelines.

A good study starts with a first-rate quality protocol. The subsequent experimental phase needs to be in line with this protocol. Finally, the report has to document the exact procedures followed, the results obtained and the conclusions drawn.

By asking **ADMERITOX** to take care of your study, **YOU** will obtain:

- a study protocol outline fully in line with your preclinical development strategy, the relevant existing data and the appropriate guidelines;
- for studies to be subcontracted:
 - selection of the Contract Research Organization according to your prerequisites and standards;

- a "meeting zero" with the study team to exclude any misunderstanding of the contents of the study protocol;
- close monitoring of the critical study phases to ensure quality in terms of science and GLP and to keep you informed of the progress and the results;
- review of the study report and tabulated summaries;
- for studies to be performed by your organization:
 - any type of support required, e.g. coaching of the Study Director, quality control, review or scientific writing of the study protocol and/or report;
- a scientific position paper in case of results that need further explanation;
- recommendations for amendment of the preclinical development plan in case of unexpected results that need further investigation.



PRECLINICAL EVALUATION AND REGULATORY DOCUMENTS

Entering a new clinical development phase or preparing an application for marketing authorization of your product requires a full and critical documentation of conducted studies and an integral safety evaluation of all available preclinical data. In addition, such an evaluation is important for the update of your preclinical development strategy.

By asking **ADMERITOX** to perform the regulatory documentation of your preclinical studies or the integral safety evaluation of your product, **YOU** will receive:

- an outline of the table of contents and the order of discussion of the conducted studies;
- a well-structured and complete preclinical regulatory document, in compliance with your writing rules and regulatory format requirements (Common Technical Document) and with fully documented quality control;
- a thorough and critical analysis of possible gaps in the preclinical study program and potential issues in the study results;
- recommendations on how to address the weak or missing elements by means of a literature search, a scientific position paper or an expert opinion;

- additional evaluations of the interrelationships between the preclinical data and clinical or chemical/pharmaceutical data, if applicable and needed.

BENEFITS

Preclinical development runs from the selection of a promising drug to regulatory submission of all generated data. Preclinical development involves numerous and quite diverse disciplines like bioanalysis, pharmacokinetics, metabolism, general toxicology and reproductive toxicology. The long preclinical development life cycle may be associated with numerous unexpected events and results, that have to be recognized at an early stage and adequately dealt with. Your organization needs all the experience, expertise and commitment it can get to make the "running of the gauntlet" as fast and as smoothly as possible.

By teaming up with **ADMERITOX**, **YOU** may expect:

- focus and first priority to your specific needs;
- input based on extensive experience and expertise in ADME and safety testing, obtained in several therapeutic areas and for several routes of administration;
- all-round support in every aspect of preclinical development of your product, thus providing continuity all the way to the final dossier;
- tangible products: quality documents at a competitive price within pre-agreed timelines.

