Approved by

The Board of Directors of RusnanoMedInvest, LLC

Minutes # 3
dated April 24, 2012

Regulation
on R&D expert review process
in RusnanoMedInvest, LLC (RMI)

Moscow

2012

1. General

1.1. The R&D expert review process shall be conducted using RMI's in-house resources and subject to the resolution of RMI's executive board – RMI's experts.

1.2. RMI experts' activity shall be governed by the RF legislation and subject to the regulations of government bodies, the present Regulation, other RMI's regulatory instruments and resolutions of RMI's executive board.

1.3. The R&D expert review process is aimed at obtaining from the experts an unbiased and evidence-based opinion in regard to the features of subjects under review pursuant to the Terms of reference (TOR) for expert review.

1.4. Objectives of R&D expert review process include:

- Assessment of trial findings of pharmaceuticals (medical products) and generation of reports on completeness, quality, efficacy and safety of subjects under review.
- Assessment of conformity of trial composition, setting, schedule and budget with requirements as envisaged by good clinical practice and R&D market supply.
- Probability of success of pharmaceuticals (medical products) based on available evidence or hypothesis of efficacy, safety and quality, and subject to the results of findings in the Russian and global markets.
- Probability of success in localization of the results of trials, production and marketing of pharmaceuticals (medical products) in the Russian Federation.
- Assessment of significance of the events to take place during clinical/non-clinical trials of pharmaceuticals (medical products), and their impact on the market launch probability of products under review.
- Related problem solving

2. Expert's functions

RMI experts shall exercise the following functions:

2.1. Expert review of documents for pharmaceuticals (medical products) pending RMI's approval and generation of expert reports.

2.2. Analysis and collection (if needed) of safety-related data on pharmaceuticals (medical products).

2.3. Recommendations on improvement of the trial program for corresponding pharmaceuticals (medical products).

2.4. Expert review of data on clinical trials of pharmaceuticals (medical products) subject to good laboratory practice (GLP) and good clinical practice (GCP) regulations.

2.5. Drawing up a proposal on improvement of the expert review concept.

2.6. Interactions with governmental, social, professional, scientific and other organizations, and institutions, and other experts within the constraints of set objectives and specified functions.

2.7. Performance of other functions as directed by RMI's executive board.

3. RMI experts' team

3.1. Number of RMI experts is not limited.

3.2. Members of RMI experts' team shall be approved at the direction of RMI's executive board.

3.3. Experts' activity shall be coordinated by a designated person to be appointed by RMI's executive board (hereinafter referred to as "the Expert review coordinator").

3.4. RMI experts' team shall be formed pursuant to both acting RF legislation and RMI's by-laws.

Any person has the right to file a letter of intent (LOI) requesting to join RMI expert's team (Attachment 1). LOIs shall be forwarded by regular mail, e-mail at RnD@nmedica.com or using corresponding RMI web-services.

LOIs shall be examined within 15 calendar days of the date of receipt. The applicant shall be informed of the results of examination via e-mail.

The applicant will receive standard contracts for signature via e-mail or otherwise subject to the order and expert review procedures if positively determined. Upon receipt of original and signed contracts the applicant shall join RMI expert's team subject to the resolution of RMI's executive board.

The expert has the right to resign from RMI expert's team at any time and for any reason whatsoever. The expert shall notify via e-mail the Expert review coordinator of such intent when occurred. Should the decision to resign from RMI expert's team be taken at the time of performance of assigned task, the completion of this task is subject to provisions of the corresponding contract negotiated between RMI and the expert.

3.5. The Expert review coordinator shall:

- Organize the work to be performed by RMI experts;
- Organize, conduct and chair RMI expert's meetings;
- Organize the work on forming RMI expert's team;
- Present to RMI's executive board materials and documents related to experts' activity;
- Draw up final reports following the results of the expert review;
- Engage other medical experts and healthcare providers in activity associated with the expert review;
- Notify RMI's executive board of the status of task performance and activity of RMI experts.

4. Rights and obligations of RMI experts

4.1. RMI expert can:

- Request for additional materials, clarifications and rationale to be provided with regard to generation of reports during the expert review process;
- Obtain information related to the subject under review, the subject under investigation, reference and information materials required in the expert review process;
- Request for specialists in applied and specialty sciences and engineering to be engaged in the expert review process;
- Propose for improvements in the expert review process and experts' activity;
- Amend draft documents;
- Form and chair RMI's working groups and expert panels;
- Conduct expert review, generate corresponding reports and make recommendations in accordance with area of expertise;
- Review issues related to RMI experts' activity and draw up information and reference materials;
- Get payment for the work performed subject to the contract and TOR for expert review process;
- Perform any other activity subject to the present Regulation

4.2. RMI expert shall:

- Adhere to the requirements as specified herein, terms of negotiated contracts and terms of reference for expert review process;
- Follow the confidentiality requirements in regard to data contained in materials of the expert review as specified in terms of the expert review procedures;
- Act on behalf of RMI in negotiations with third party only upon the written consent of the Expert review coordinator

4.3. All RMI experts shall conduct the expert review subject to contracts negotiated with RMI.

4.4. RMI experts shall conduct expert review pursuant to TOR personally and subject to no option of replacement.

5. RMI experts' activity arrangements. Rules for conducting the expert review

5.1. The expert review shall be conducted by an expert subject to TOR for expert review signed by the Expert review coordinator. TOR for expert review shall include:

- Identification of a type and a subject under review, questions to an expert;
- Expert review timelines;
- Feasible expert review peculiarities;
- Other information required for the expert review.

5.2. Payment for the expert review activity shall be made subject to corresponding contract terms.

5.3. TOR for expert review shall be given at the discretion of the Expert review coordinator as the case may be. RMI is not obliged to give TORs to each and every expert.

5.4. Organizational and expert review performance requirements:

- Independence and legal safety of subjects of expert review in the course of their professional activity;
- Scientific approach, completeness, consistency and credibility of expert review subjects examination, and feasibility control of the expert review results;
- Competence and high level of expertise;
- Organizational complexity of the expert work and its methodological support;
- Focus on the global level of science and industry developments, norms and regulations of environmental, technical and social safety, the compliance with the RF and other countries legislation, and applicable international and national standards;

5.5. Important violations of the expert review performance are:

- Adulteration of materials, information and data provided for the expert review;
- Enforcement of an expert to generate a misleading expert report;
- Impeding the performance of the expert review;
- Inconsistency of the expert report conclusions;
- Falsification of the expert report conclusions;
- Withholding grounds for the expert disqualification (when affiliated or subject to potential interest in biased results of the expert review);
- Direct or indirect interference with the expert review process aimed at influencing the process and the results of the expert review;
- Other violations subject to liability pursuant to the RF legislation.

5.6. Organizational and technical support, including premises, facilities, and personnel shall be provided by RMI.

5.7. The meetings of RMI experts may be conducted by the Expert review coordinator in an ordinary format or by means of communication in accordance with the agenda.

5.8. The Expert review coordinator shall inform the experts of time and place of the meeting as well as the agenda items to be reviewed during the meeting and submit draft documents at least 7 calendar days in advance of the meeting date.

Draft documents and information contained therein as part of the preparation procedure to the ordinary meeting shall be subject to public non-disclosure. Information disclosed to the experts in regard to the performance of the expert review is strictly confidential and is subject to non-disclosure. Confidential documents to be sent to experts shall be numbered and available (returned) against the expert's signature.

Should the expert fail to come to the meeting he shall notify the Expert review coordinator at least 2 working days in advance of the meeting date.

Should the expert fail to be present at the meeting the expert may send his opinion on the agenda item in writing. This opinion shall be subject to review at the meeting and shall be considered in the decision-making process.

5.9. RMI's executive board tasks orders shall be reviewed at meetings as a matter of priority.

5.10. RMI expert(s) having an interest in a decision to be taken on any of the agenda items shall notify the Expert review coordinator immediately.

5.11. The Expert review coordinator has the right to postpone the review of an agenda item and may resolve on the reconsideration with firm date specified and subject to the following:

- Need for subsequent expert review of documents provided;
- Need for extra documents to be received;
- Failure to review the item for another reason.

6. Expert's interaction with the executive board of RusnanoMedInvest, LLC

6.1. Experts' conclusions are non-regulatory.

6.2. RMI employees have the right to participate in RMI experts' meetings.

6.3. The Expert review coordinator has the right to address issues associated with the expert review to RMI's executive board.

6.4. The Expert review coordinator has the right to participate in RMI meetings subject to topics associated with the expert review results conducted by the Expert Council members.

6.5. The Expert review coordinator shall coordinate relations of RMI experts with other RMI advisory bodies or committees or any other organization as directed by RMI's executive board.

Attachment 1
To R&D experts' review process in RusnanoMedInvest, LLC

Letter of intent
To join the expert team of RusnanoMedInvest, LLC (RMI)

I, the undersigned, inform of my intent to join the expert team of RMI, LLC. I hereby give permission to use my personal data given below subject to RMI expert activities only, including

- Need for RMI to follow labor and civil legislation requirements;
- Need to settle accounts with me for the work performed as an RMI expert;
- Need to publish data as part of various RMI reference materials, including corporate website within the period of my membership in RMI experts' team (duration of a contract).

Full name	
Date of birth	
Passport data (any other ID document)	
TIN	
Insurance Number of Individual Ledger Account (СНИЛС)	
Address for service	
E-mail	
Phone	
Website (if any)	
Academic degree	
Academic rank	
Primary employment, address	
Area of expertise/Profile (indicate all specialties where you possess expert knowledge and skills)	
Total # of publications/in peer-reviewed journals/in international journals/# of monographs or books (personal or in co-authorship)	
Level of English proficiency (fluent/basic/none)	

Signature Date