CIMT
Immunologische Krebs-Therapie e.V.

Langenbeckstr. 1
55131 Mainz

Satzung

Preamble

The Regulatory Research Group („RRG“) is an **independent group of experts** focusing on regulatory aspects of drug development in the field of immunotherapy. The individual members of the group have a **specific expertise** in drug development or immunotherapy. The group is (and will always) be **open** for any experts committed to contribute to the goals of the RRG. Each individual (before becoming a member of the RRG) has to agree that every action and input contributed as a member with RRG activities is intended to support **scientific or medical progress** in the field of **immunotherapy**.
Independency and **transparency** are basic principles on which all RRG activities are based on.
Members participating in any RRG activity must therefore **at all time refrain from** acting as a **lobbyist** or **stakeholder** pursuing commercial goals or promoting the development of specific drug products, diagnostic tests or medical devices.
Every **potential conflict of interest** will have to be **disclaimed** before becoming a member of the RRG and during the time of membership in the Group.
RRG activities should **not include** discussion of **details** and **information** related to an ongoing or future **development of a specific product** but solely address the **generic principles** and **publicly available information** on (international/national) laws, directives and regulations influencing the development of immunotherapy.
All relevant activities of RRG and all relevant documents generated by RRG members within RRG activities will be made publicly available via the website of the Association for Cancer Immunotherapy (www.c-imt.org).
RRG activities will be conducted under the **organizational umbrella** of the Association for Cancer Immunotherapy (CIMT), a non-profit Association located in Mainz (Germany).
Although CIMT is providing the organizational framework, no CIMT executive, member or sponsor has the right to interfere by any means with the independent activities of RRG.

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1) Goals

The main goals of RRG are

(1) to support the advancement of immunotherapy,
(2) to gain and maintain a deep understanding in regulatory principles ruling the development of new therapies,
(3) to conduct a science-driven critical review of existing regulatory documents,
(4) to support and initiate educational activities of drug development,
(5) to identify critical questions in quality, pre-clinical, and clinical development of immunotherapy,
(6) to work out solutions to regulatory challenges of innovation and
(7) to disseminate knowledge generated within the RRG.

The RRG members acknowledge that the development of patient-oriented approaches as well as advanced therapy medicinal products, while bearing a high potential for improvement of patient treatments, can be a complex challenge and need extremely careful considerations at all stages of clinical development. Especially academic institutions and small and medium sized enterprises in which many of the innovative therapies are conceived and developed at an early stage are struggling to built up the necessary in house expertise and professional structures needed to successfully develop new therapeutic medicinal products. Members of the RRG will therefore preferentially focus on finding solutions to support and facilitate the safe and effective development of innovative approaches at early stages of product development.

2) RRG Activities

2.1) Meetings

The members of the RRG will organize and participate at regular (2-3 per year) meetings with a defined agenda. The date, location and agenda of RRG meetings should be announced in advance at the CIMT website (www.c-imt.org). Once in a year an overview of topics discussed, documents published and conclusions drawn will be given at the annual CIMT meeting which is openly accessible.

2.2) Review of Regulatory Documents

The members of the RRG will critically review existing and newly emerging documents published by regulatory authorities world-wide. One major focus will be the review of new documents which are undergoing a public consultation period.

2.3) Education

The RRG will organize workshops and conferences for basic scientists, drug developers, and healthcare professionals.

2.4) Publications

The RRG is aiming to write and publish position papers to regulatory guidelines and wants to contribute input into existing public consultation pathways. RRG publications should (whenever possible) made publicly available.

2.5) RRG research

The RRG will initiate independent research projects focusing on specific questions related to regulatory aspects of drug development. Funding of such research projects will have to be exclusively covered by public foundations or non-profit organizations.

2.6) Collaborations

The RRG is open to co-operations with individuals and groups and organizations that share the same goals whenever collaboration supports the achievement of RRG goals and does not interfere with the RRG basic principles of full independency and transparency.

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3) Finances and support

The CIMT will support the organization of the RRG meetings, the presentation of results during the annual CIMT meeting, and the organization of a scientific session with invited international and national speakers with a maximum budget of 10.000,00 Euro (ten thousand) per year. RRG activities exceeding this basic budget will have to be co vered by funding through public funding agencies and non-profit organizations.

4) Membership and Responsibilities

4.1) Committee

Every three years the RRG appoints a committee consisting of one or two chair(s) and one or two scientific secretaries. The 2-4 RRG committee members will be elected at the first RRG meeting in the year 2010. Each member will have one vote. Speaker(s) and Sci entific secretary(s) of the RRG will have to be appointed by a majority vote (more than half of participants voting for the candidates). In case more than two candidate get a sufficient number of votes the two candidates with the most votes will be appointed.

4.2) Responsibilities

The speaker(s) are responsible for all RRG activities including composing the agenda of the RRG meetings, the overview of the RRG activities at the CIMT annual meeting and the organization of scientific sessions and workshops. Although the described tasks can be delegated the responsibility for the action remains by the speaker(s).
The scientific secretary(s) is responsible to keep an actual list of members (including information on proven expertise, disclaimed potential conflict of interests and agree ment to refrain from pursuing commercial goals). Further duties are to announce RRG meetings at the CIMT homepage.

4.3) Membership

Membership to the RRG is free of charge and open to any individual with proven ex pertise in the regulation of drug development and immunotherapy. Individuals that wish to become members should send a written application together with recent curri culum vitae to the CIMT office and the chair(s) of the group. Provided that applicant has (1) proven expertise, (2) openly declaimed all potential conflicts of interest and (3) agreed to restrain from pursuing any commercial interest while participating in RRG tivities, the application will be considered for acceptance at the next RRG meeting following the submission of the application. The final decision is made by vote of the participants of the RRG meeting (majority of votes from participating members needed) that has to be finally approved by the speaker(s) to become valid. Membership can be terminated at any time by notifying one of the committee members in written form. Elected members of the RRG that clearly act against the RRG statutes (“misbehavior”) can be excluded from further membership. Whenever there is evidence of such “misbe-havior” the case should be made aware to the chair(s). The chair(s) are responsible to either propose a strategy to make sure that misbehavior does not happen again or to pro-pose exclusion of the member from further RRG activities. The chair’s proposal has to be approved by the members by majority vote. If the majority of members does not approve the chair’s proposal the chair has to come up with a modified proposal.

This RRG statute became effective after 1.1.2010