PMT STUDY INTELLECTUAL PROPERTY GUIDELINES

Background and Purpose

These intellectual property guidelines take into account those in place as established by the European Network for the Study of Adrenal Tumours (ENSαT) (Version July 8th, 2011). Since the PMT study involves a small multicentre network with well-established objectives, the guidelines here represent more of a non-binding "gentleman's agreement" than the firm stipulations outlined under the ENSαT guidelines.

Access to collected data

Access to data: At least one member from each participating centre has full access to all data collected into the PMT study database. Such data should be regarded as confidential and should not be circulated to others outside of the PMT study protocol without prior approval from lead investigators at all other participating centres. This restriction does not apply to those data automatically downloaded from PME eCRFs to ENSαT registries. Those data are subject to ENSαT intellectual property guidelines.

Use of collected data

Use of own data: Members from each participating centre are free at their own discretion to use the data collected from the patients enrolled at their own centres for purposes of public dissemination (e.g., oral presentations and publications). This includes all biochemical data. Nevertheless, the objectives and data presented in such communications should not conflict or detract from planned communications derived from the multicentre collaborations outlined under the already stated objectives of the PMT protocol. Moreover, should a communication be planned that utilises such data, then the responsible lead investigator should in a show of good faith notify and seek agreement from lead investigators at the other participating centres.

Use of data collected by other centres: Members from each participating centre should not use for public dissemination data collected from other centres without prior clear written approval (email is sufficient) from the lead investigators of the other centres. Manuscripts produced using such data should be circulated for comment and approval before submission. The contributions of members of other centres should be acknowledged appropriately, as outlined in the guidelines on authorship below.

Authorship

Lead centres for authorship: The primary objectives of the PMT protocol (as outlined in the Dresden version) reflect those formulated by the three initiating centres: Dresden, Nijmegen, Warsaw. As such these initiating centres bear the primary responsibility for compiling and writing up the data collected for manuscripts that address those objectives. Other participating centres have established additional objectives (e.g., metabolomics at Munich; immunoassay vs HPLC & LC-MS/MS at Würzburg) and it is expected that those centres will bear responsibility as the lead centres for authorship of communications that address those objectives. The PMT study is expected to provide data for numerous other sub-projects and communications that have yet to be realized or considered. Members of the PMT study network are encouraged to identify such sub-projects and thereafter take responsibility as lead centres for any such resulting communications.

Justifications for authorship: Participation in the PMT protocol does not automatically justify authorship unless that participation involves a significant contribution to the collection of useable patient data. As a general rule, in order to justify inclusion for authorship, each participating centre should contribute at least 5% of the patient data to the particular sub-project. Additionally, those data should be reasonably complete in order to satisfy the particular objectives of the specific sub-project. For example, for the sub-project addressing biochemical-cardiovascular relationships, coauthorship cannot be expected if the collected cardiovascular data are incomplete so as to exclude those data from the analyses (e.g., there is only one blood pressure measurement when three are required in the eCRFs to satisfy the guidelines necessary for publication). An acknowledgement should suffice in situations where contributions are insufficient to justify authorship.

Authorship positions: The first author should bear the primary responsibility for writing or initial drafting of the manuscript, and should in general be a member of the lead centre. Second and last authors are expected to have made major contributions to collection and interpretation of data and the writing of the manuscript and may include members of associated lead centres or other centres that have contributed substantially to data collection. Lead investigators at each participating centre should provide recommendations about who from their participating centre deserves to be listed as a coauthor and who should rather be acknowledged. As a general rule, authorship positions together with numbers of authors from each centre should also be considered together and guided by the relative contributions of each centre and individuals at each centre to the study planning and collections of patient materials and data.

Authors from outside of patient accrual centres: Positions of authorship may also be granted to investigators outside of participating centres who have not contributed to patient accrual. This could for example include contributions to mutation testing, pathological examinations, analyses of imaging data and statistical assistance.