**IIR Assessment Form for preclinical studies**

*The format of this form can be modified, yet the criteria mentioned herein are considered minimum. Information required to be obtained about an IIR prior to Second-tier Review.*

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| **Document history** |
| Original version:  Date of request: *Add* |

In case of re-submission: changes compared to original version:

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| Change 1 | *Describe* |
| Change 2 | *Describe* |

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| **General information** | | | |
| * Please provide information for all items marked “**M**” (mandatory). Items marked “**O**” are optional. * Fields colored in yellow need to be completed in Mont Blanc for the submission of a new IIR concept. | | | |
| M | **Investigator/institution** | | |
|  |  | *Name, Title, Address, Phone, E-mail* | |
| O | **Contact person (if applicable)** | | |
|  |  | *Name, Title, Address, Phone, E-mail* | |
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|  |  |  | |
| M | **Short Title** | | |
|  |  | *Provide the abbreviated title of the study (max. 60 characters)* | |
| M | **Protocol title** | | |
|  |  | *Provide the full title of the study* | |
| M | **Product(s) used in Study** | | |
|  |  | *Please select one of the following items:*   * *Bayer drug(s) are used,* * *Bayer and Non-Bayer drugs,* * *No drug(s) used or* * *Non-Bayer drug(s) used* | |
| M | **Related Bayer Product** | | |
|  |  | *In order to correctly channel your study proposal at Bayer, please indicate the Bayer product, where the study is most related to (even if no Bayer drug is used).* | |
| M | **Bayer drug(s) or Non-Bayer drug(s) used as comparator/ additional study drug(s)** | | |
|  |  | *Enter all additional Bayer or Non-Bayer drugs that are used in the study* | |
| M | **Indication / disease** | | |
|  |  | *Provide the specific indication, pathological entity or diagnostic procedure to be studied* | |
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| O | **IIR Responsible** | | *Add name of IIR Responsible (if already available)* |
| M | **Primary country** | | |
|  | *Indicate the primary country* | | |
| M | **Planned number of countries** | | |
|  | * *Please enter the number of countries that are planned to participate:* * *Indicate the planned participating countries:* | | |
| M | **Planned number of samples** | | |
|  | *Please enter the number of planned samples* | | |
| M | **Blinding & Control** | | |
|  | *Please enter for example “uncontrolled, non-blinded, blinded…* | | |

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| O | **Additional Author(s)** | *Additional Author(s) of study protocol* |
| O | **Investigator Operations Manager email** | *Email of a non-Bayer employee that will assist with managing the study the system.* |

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| **IIR Support** | |
| M | **Support Requested from Bayer** |
|  | *Please select one more of the following items:*   * *Analytical* * *Financial* * *Medicinal Product/ substance* * *Equipment* * *Other, please describe* |
| M | **Is the study financially supported by other organizations?** |
|  |  |
| M | **Total Study Cost:** |
|  |  |
| M | **Estimated Amount requested from Bayer (Currency):** |
|  |  |
| M | **Detailed Budget Plan** |
|  | *Please add* |

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| **Rationale and objectives** | | |
| M | **Rationale** | |
|  |  | * *Provide a brief statement (maximum 1 page) of the scientific reasons that make it advisable to conduct the proposed study. State the question to be answered by the study or the hypothesis to be proved or disproved by it. A summary of the known and potential risks and benefits should be provided or indicate where this information can be found.* * *Please comment on the translational aspect (to the clinic/ patients).* |
| M | **Goals / Objectives** | |
|  |  | * *Provide the goals or objectives and their detailed description* * *Please describe use in vitro, in vivo, in situ etc.* |
| M | **Human Material Included?** *Yes/ No* | |
| O | **Study design/ Experimental** | |
|  |  | *Please provide the following information:*   * *Describe study design* * *Please describe whether human material/probes are used (if applicable)* * *If in vivo: please provide specifics and route for administration* * *Origin of models* * *Quality controls for cell lines/models* * *Reference compounds (w/provider)* |
| O | **Keywords** | |
|  |  | *Please describe* |

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| **Statistical analysis** | | |
| M | **Statistical & Analytical Plan and Methodology** | |
|  |  | *Describe the analysis plan. Briefly describe the statistical methodology to be used, including handling of missing information. If any of the methods are not standard, provide references.*  *Include sample size and power considerations, if applicable* |

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| **Timelines** | | |
| M | **Planned Study Timelines:** | |
|  |  | 1. *Submission date to health/ animal/ ethics authority submissions (if applicable)* 2. *Please provide a plan for the different experiments if applicable* 3. *Start of experiment(s) date* 4. *End of experiment(s) date* 5. *Report date* 6. *Planned publication /presentation date* |

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| **Material request** | | |
| M | **Bayer Medicinal product(s) and amount being requested:** | |
|  |  | * *Please also provide the shipment address* * *Please provide Institutional Office for Legal Affairs/ Technology Transfer (Name, Title, Department, Institution, Address, Phone, E-mail)* |