**IIR Assessment Form – Clinical Studies (interventional or observational)**

*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** | | |
|  |  | *Name, Title, Address, Phone, E-mail* | |
| M | **IIR Type***;* | | |
|  |  | *Interventional; Observational;* | |
| M | **IIR Subtype** | | *Indicate whether the study Retrospective, Prospective study or Retrospective-prospective:*   * ***Retrospective:***   *A study where data collection is initiated and completed prior to study start (FPFV and LPLV occur before study start).*   * ***Retrospective-prospective:***   *A study where data collection is initiated prior to study start (FPFV occurs before study start) but ended after study start (LPLV occurs after study start)*   * ***Prospective:***   *A study where data collection is initiated and completed after study start (FPFV and LPLV occur after study start) The STUDY START date corresponds to the date with study activities are initiated (following all study approvals)* |
| 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 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) - details on formulation and strength are required* | |
| 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 (details on formulation and strength as well as need for placebo are required)* | |
| M | **Indication** | | |
|  |  | *Provide the specific indication, pathological entity or diagnostic procedure to be studied* | |
| M | **Phase of Study** | | |
|  | *Indicate whether Phase I, I/II, I/III, II/III, IIa, IIb, III, IV or not applicable* | | |
| O | **IIR Responsible** | | *Add name of IIR Responsible (if already available)* |
| M | **Primary country** | | |
|  | *Indicate the primary country (where the IIR is conducted)* | | |
| M | **List of planned countries** | | |
|  | * *Please enter the number of countries that are planned to participate:* * *Indicate the planned participating countries:* | | |
| M | **Planned number of sites/ subjects** | | |
|  | *Enter the planned number of subjects:*  *Enter the planned number of sites:* | | |
| M | **Blinding & Control** | | |
|  | *Indicate if the study is randomized/non-randomized, single-blind/double-blind/open, uncontrolled/placebo-controlled, etc.* | | |
| M | **Is a preclinical part included? If yes, please describe** | | |
|  |  | *Yes/ No*  Note to the IIR Responsible: it needs to be decided case by case if the IIR Assessment form pre-clinical needs to be completed in addition | |

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| M | **Study exploring new combinations, alternative dosing / dosing schedules or new formulations** | | *Yes / No* |
| M | **Study with clinical pharmacology objectives, including biomarker, pharmacokinetic (PK) or pharmacodynamics (PD) evaluations** | | *Yes / No* |
| 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 or more of the following items:*   * *Analytical* * *Financial* * *Investigational Medicinal Product / Placebo / pure drug substance* * *Equipment* * *Other, please describe* |
| M | **Is the study financially supported by other organizations?** |
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| M | **Total Study Cost:** |
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| M | **Estimated Amount requested from Bayer (Currency):** |
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| M | **Detailed Budget Plan** |
|  | *Please add* |

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| **Rationale and objectives** | | |
| O | **Please explain why this study is non-blinded/masked (if applicable):** | |
| M | **Study Type and Design** | |
|  |  | *Describe the type (e.g.: interventional, observational, retrospective, etc.) and the design (e.g., parallel group, crossover, intra-individual, matched groups etc.) utilized for the study* |
| M | **Rationale** | |
|  |  | *Provide a brief statement (maximum 1 page) of the medical and 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. Describe the clinical setting.* |
| M | **Primary Study Objective(s)** | |
|  |  | *Provide the primary objective and their detailed description* |
| O | **Secondary Study Objective(s)** | |
|  |  | *Provide the secondary objective(s) a detailed description of it/them* |
| M | **Study operational /organizational aspects** | |
|  |  | *Describe the organizational aspects of the study: Structure (e.g., multicenter, multinational); the number of centers and planned Country(ies); who will conduct the study; who will perform the monitoring, etc.* |
| O | **Keywords** | |
|  |  | *Please describe* |
| **Population and methods** | | |
| M | **Study Population** | |
|  |  | *Description of the population to be included in the study and the foreseen number of cases (per arm, when applicable)* |
| M | **Inclusion Criteria (detailed)** | |
|  |  | *Complete set of criteria to be fulfilled by a potential subject or patient to be included in the study. State specific diagnostic/disease criteria when relevant. For unusual or novel criteria, provide rationale* |
| M | **Exclusion Criteria** | |
|  |  | *Complete list of criteria that would prevent the inclusion of the potential subject or patient in the study, should any of them be present. Provide rationale for unusual exclusion criteria* |
| M | **Investigated Treatment(s)** | |
|  |  | *Describe the investigated treatment(s) as accurately as possible including pharmaceutical form, strength, dose, timing, route and schedule of administration. When applicable, indicate maximal daily dose* |
| O | **Investigated Treatment(s): Rationale for unusual or novel approaches** | |
|  |  | *Provide a rationale for the selection of the novel or unusual treatment(s), (which would be studied via an observational design)* |
| M | **Request for Bayer Medicinal Product/Substance Supply** | |
|  |  | *Provide information with regard to investigational product/placebo (name of products, details on formulation and strength, packaging, quantity are required). Furthermore, details regarding complete manufacturing chain/steps done at Bayer or at the sponsor are required* |
| M | **Reference Treatment or Modality/Treatment or Modality of Comparison (Description)** | |
|  |  | *Describe the treatment of reference or comparison as accurately as the test treatment. Describe any reference (comparative) modality. For non-comparative studies, state “Not applicable”* |

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| **Safety reporting** | | |
| M |  | **Safety reporting** |
|  |  | *Provide a description of what adverse events (AEs) will be collected and reported to the sponsor in an expedited manner and what (serious) AEs will be exempted from reporting (e.g. efficacy and safety outcomes, non-serious AEs).*  *Provide information on what adverse events will be reported to the Ethics Committee(s) and/or competent authorities, who will be responsible for submission thereof and in what timelines. Reference is to be made to GCP regulations (if applicable) and other regulations (global and/or local).*  *Interventional or observational character of the study should be considered for applicability of reporting rules. For observational trials use of data (primary or secondary data collection) should be considered.*  *Please consider reporting of device incidents/MDR (medical device report) reportable events.* |

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| **Statistical analysis** | | |
| O/M | **Standard of Reference/Standard of Truth\*** | |
|  |  | *Provide a detailed description of any standard used (standard of reference and/or standard of truth) \* mandatory for Diagnostic Imaging studies* |
| M | **Rationale for selection of a reference treatment** | |
|  |  | *For comparative studies, provide a rationale for the selection of the reference treatment* |
| M | **Assignment of subjects to study arms or groups (Randomization/Stratification)** | |
|  |  | *Describe the method for assigning patients to the various treatments in the clinical study and blinded read, if applicable* |
| M | **Blinding** | |
|  |  | *Indicate the level and method of blinding/masking (e.g., open-label, single-blind, double-blind, observer-blind, etc.). Describe reasons and implications if blinding is unnecessary or not feasible* |
| M | **Concomitant Treatment(s)** | |
|  |  | *Describe as accurately as possible stating the criteria or circumstances in which it should be used. If no concomitant treatments are foreseen, state “Not applicable”* |
| M | **Primary Outcome(s)** | |
|  |  | *Provide a detailed description of the primary outcomes(s). If there is more than 1 primary outcome, indicate how issues of multiplicity will be resolved* |
| O | **Secondary Outcome(s)** | |
|  |  | *Provide a list of the secondary outcomes(s) including detailed description(s)*  *Note: The number of secondary outcomes should be limited (i.e. not more than 6).* |
| M | **Safety Outcomes** | |
|  |  | *Indicate the safety variables that will be collected to assess safety (laboratory values, ECG, vital signs, etc.)* |
| O | **Measurement of results (How assessed)** | |
|  |  | *All efficacy and safety variables to be assessed and laboratory tests to be conducted, their schedule, the methods for measuring them, and the persons responsible for the measurements should be identified.*  *Any specific instructions to the patients /rate trainings should be noted.* |
| M | **Visit schedule** | |
|  |  | *Describe here the foreseen visit schedule and main activities foreseen at each visit* |
| M | **Follow-up period** | |
|  |  | *Brief description of time frame and scheduled activities for the follow-up period* |
| 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:** | |
|  |  | *For prospective studies:*   1. *Approval date/submission/ to health authority/ethics* 2. *First Patient First Visit date* 3. *First Patient Last Visit date* 4. *Last Patient Last Visit date* 5. *Report(s) date* 6. *Planned Publication(s)/presentation(s) date*   *For retrospective studies or hybrid studies (retrospective-prospective)*   1. *Submission date to health authority/ethics* 2. *Dates when data collection is initiated and completed  (time when patients were under treatment (under observation) e.g. 1.1.2010 – 31.12.2016)* 3. *Start of Retrospective study* 4. *End of Retrospective study* 5. *Report(s) date* 6. *Publication(s)/presentation(s) date* |

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| **Limitations** | | |
| O | **Criteria for selection of evaluable cases** | |
|  |  | *Describe the selection of patients to be included in the analyses (e.g., all randomized patients, all dosed patients, all eligible patients, all evaluable patients). If there are any planned reasons for excluding from analysis patients for whom data are available, these should be stated. If there are any subgroups whose results are to be examined separately, these should be identified.* |
| M | **Interim Analyses (if applicable)** | |
|  |  | Describe any interim analyses that will be performed including the methodology for maintaining the integrity of the study (e.g., Data and Safety Monitoring Boards) and protecting the overall significance level (e.g., statistical stopping rules) |
| M | **Number of Evaluable Patients (estimate):** | |
| M | **Sample Size Assumptions/Target Number of Valid Cases**  **(incl. Power and Confidence)** | |
|  |  | *Indicate the number of evaluable patients that is required for the primary efficacy variable. This number should correspond to the number of evaluable patients (estimate). Give method of sample size calculation incl. level of significance and power* |
| M | **Health Economic Variables (if applicable)** | |
|  |  | *Indicate the health economic variables that will be collected to support reimbursement (epidemiology, patient preferences, patient reported outcomes, quality of life, burden of illness, health services research, costs, budget impact etc.) or describe why collecting health economic variables is not possible/reasonable* |