**IIR Assessment Form – COVID-19 Clinical Research**

This Form is designed to support and coordinate the operational management of review and approval of requests for Investigator-Initiated Research for COVID-19 and corresponding decisions during the period of the COVID-19 emergency situation. This Form is to be used with the guidance COVID\_CAT\_10b\_COVID\_Clincal IIR\_General Guidance.

Form given below is related to the following Quality System Document in QDoc:

* RD-SOP-1257 “Manage proposal and support for investigator/institution initiated research.”

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| **General information** |
| * Please provide information for all items marked “**M**” (mandatory) within study proposal.
* Fields colored in yellow need to be completed in this form.
 |
| M | **Investigator/institution**  |
|  |  | *Name, Title, Address, Phone, E-mail* |
| M | **Contact person** |
|  |  | *Name, Title, Address, Phone, E-mail* |
| M | **IIR Type** [ ] Interventional [ ]  Observational |
| M | **IIR Subtype** | [ ]  **Retrospective**[ ]  **Retrospective-prospective:** [ ]  **Prospective:**  |
| M | **Short Title:** |
| M | **Protocol title:** |
| M | **Product(s) used in Study:** |
| M | **Related Product (name, formulation, strength):** |
| M | **Bayer drugs or Non-Bayer drugs used as comparator/ additional study drugs (name, formulation, strength):** |
| M | **Phase of Study**  [ ]  I, [ ]  I/II, [ ]  I/III, [ ]  II/III, [ ]  IIa, [ ]  IIb, [ ]  III, [ ]  IV [ ]  not applicable |
| M | **Primary country:** |
| M | **List of planned countries (participating/number):** |
| M | **Planned number of sites/ subjects:** |
| M | **Blinding & Control**  |
| M | **Is a preclinical part included?** [ ]  **Yes** [ ]  **No If yes, please describe within proposal.** |

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| **IIR Support** |
| M | **Support Requested from Bayer** |
|  | [ ]  Analytical [ ]  Financial [ ]  Investigational Medicinal Product [ ]  Placebo [ ]  pure drug substance [ ]  Equipment [ ]  Other, please describe within proposal |
| M | **Total Study Cost:**  |
| M | **Estimated Amount requested from Bayer (Currency):** |
| M | **Detailed Budget Plan**  |

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| **Please give information about the following topics within proposal** |
| M | **Study Type and Design** |
| M | **Rationale**  |
| M | **Primary Study Objective(s) & Secondary Study Objective(s)** |
| M | **Study operational /organizational aspects** |
| M | **Study Population** |
| M | **Inclusion Criteria (detailed)** |
| M | **Exclusion Criteria** |
| M | **Investigated Treatment(s)**  |
| M | **Request for Bayer Medicinal Product/Substance Supply** |
|  |  | **name:****formulation:****strength:****packaging:****quantity:** |
| M | **Reference Treatment or Modality/Treatment or Modality of Comparison (Description)** |
| 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 |
| M | **Safety reporting**  |
| M | **Rationale for selection of a reference treatment** |
| M | **Assignment of subjects to study arms or groups (Randomization/Stratification)** |
| M | **Blinding** |
| M | **Concomitant Treatment(s)** |
| M | **Primary Outcome(s) & Secondary Outcome(s) & Safety Outcomes** |
| M | **Measurement of results (How assessed)** |
| M | **Visit schedule & Follow-up period** |
| M | **Statistical & Analytical Plan and Methodology** |
| M | **Planned Study Timelines:** |
|  |  | *For prospective studies:*1. *Approval date/submission/ to HA/EC*
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 Publication(s)/presentation(s) date*
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| M | **Interim Analyses (if applicable)** |
| M | **Number of Evaluable Patients (estimate):** |
| M | **Sample Size Assumptions/Target Number of Valid Cases (incl. Power and Confidence)** |
| M | **Health Economic Variables (if applicable)** |

Revision History

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| **Version N°** | **Effective Date** | **Document Section**  | **Changes to former version** |
| 1.0 | 31 March 2020 | NA | NA |
| 2.0 | 09 April 2020 | Title Updated and minor change to paragraph one | Changed “Study” to “Research”:IIR Assessment Form – COVID-19 Clinical “Research” and Investigator-Initiated “Research”  |
| 3.0 | 17 February 2021 | Revision History | Updated Revision History Table with dates  |