**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* | |
| 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 |