**ACTD Part III: Non-Clinical Documentation - Good Laboratory Practice (GLP) Compliance Form**

***To be filled by applicant***

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| Product Name | **:** |
| LOI Number | **:** |
| Active Ingredient(s) | **:** |
| Applicant | **:** |

* Pivotal non-clinical safety studies for New Chemical Entity (NCE), Biologics and Natural Products with Therapeutic Claim must be conducted in a facility which complies to Organisation for Economic Cooperation and Development (OECD) Good Laboratory Practice (GLP) requirement as mentioned in Directive No. 9, 2016, Bil. (40) dlm.BPFK/PPP/07/25.
* Pivotal Non-Clinical safety studies shall include all studies submitted in QUEST system (under PART III: Non-Clinical Documentation) except Primary and Secondary Pharmacodynamics studies.
* The non-clinical study report should indicate the extent of compliance of the reported data with the OECD Principles of GLP. A declaration of OECD GLP compliance status should be attached in QUEST system in E14: Other supporting documents during the initial evaluation (screening process). The declaration should contain the following statement (or using any other expression with the same meaning):

“Study was conducted in accordance or in compliance with the OECD Principles of GLP”.

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| **No.** | **Study title & Study number** | **Date of completion of final report** | **Test facility site(s)**  **(Name and full address - state all sites)** | **Period in which the**  **test facility/test**  **site was used** | **GLP compliance to OECD (Yes/No\*)**  **\*Provide justification** |
| **Safety Pharmacology** | | | | | |
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| **Toxicology** | | | | | |
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| **Others** | | | |  | |
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