# In Vivo Pre-clinical Study Service Quotation Request Form

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| **In order to ensure the efficiency of the quotation, please fill in the following questions in as much detail as possible, our technical manager will evaluate based on the information you provide, and send the evaluation results to your email as soon as possible. If you have any questions, please feel free to contact the technical support responsible for you. Thank you for your trust and support to GenScript Probio !**  |

**Note:**

**Customer information：**

|  |  |
| --- | --- |
| **Name:** |  |
| **Institution:** |  |
| **Address:** |  |
| **Phone:** |  |
| **E-mail:** |  |

**Service information（\*Essential information）：**

|  |
| --- |
| **1、The type of your drug\*:**[ ]  Monoclonal antibody [ ]  Bispecific antibody [ ]  Protein [ ]  Peptide [ ]  XDC (ADC/PDC/RDC, etc.) [ ]  Cell therapy [ ]  Gene therapy [ ]  LNP ([ ] with new molecules [ ] No new molecule ) [ ]  mRNA [ ]  Vaccine [ ]  Other**2、Drug target\*:** **3、Do you have an Reference Listed Drug for your project :**[ ]  Yes we have one[ ]  No it is totally new [ ]  I don’t know**4、Clinically expected indications /mechanism of action \*:** (This is a required item if there is a demand for medicinal efficacy) [ ]  I don’t know**5、Clinical Usage (Planned) \*:** **Administration route:**  **Dosing frequency:**  **Dosage:**  **Cycle:** **6、The progress of your pipeline\*:**[ ]  Project establishment Optimize the candidates [ ]  Obtain the candidate [ ]  CMC process [ ]  Other**7、Project requirement\*:** (multiple choice)[ ]  Pharmacodynamics (PD) [ ]  Pharmacokinetics (PK) [ ]  Toxicity (Tox)[ ]  Other**8、Drug Registration Classification \* :**[ ] New molecular (Class I)[ ] Biosimilars (Class II )[ ] Other**9、Planned launch time :** **10、Relevant species (or mRNA expression protein)\*:**[ ]  Mouse [ ]  Rat [ ]  Cynomolgus [ ]  Beagle dog [ ]  Rabbit [ ]  None [ ]  I don’t know [ ]  Other**11、Whether there are early research results related to in vivo PD, PK and toxicology**[ ] Yes (will provide the research summary)[ ] None**12、Do you want to declare? \*:** [ ]  Yes ( **12.1 Declare agency**  [ ] NMPA [ ] FDA [ ] EMA [ ] Other  **12.2 Write IND filing package** [ ] Yes [ ] No) [ ] No**13、The budget for this quotation:** **14、In addition to the information briefly described above, is there a detailed research plan :**  **15、Excipient or vehicle information:** Please provide detailed preparation or dilution methods if it is necessary to vigorously prepare or dilute the preparation of the test product.  **16、Other special needs:**   |

**If you need PD study, please fill in this information form (\* is required):**

**1、Available animal models (cell lines, modeling method, etc.) \*:**

[ ]  Can provide [ ]  Can’t provide [ ]  I don’t know

**2、Key reagents for PD detection (cell line, vehicle, reference drug, Isotype, etc.) \*:**

[ ]  Can provide [ ]  Can’t provide [ ]  I don’t know

**3、Whether to collect tissues and organs (tumor, serum / plasma / blood, organs, etc.)\* :**

[ ]  Yes  [ ]  No [ ]  I don’t know

**4、Other detection (TIL, pathological detection, PK/PD, etc.) :**

[ ]  Yes  [ ]  No [ ]  I don’t know

**5、PD results in discovery period:**

 (cell lines, TGI%, or Reference…)

**6、Other requirement:**

**If you need PK study, please fill in this information form (\* is required):**

**1、Key reagents for PK detection (coated antigen, secondary antibody, etc.) \*:**

[ ]  Can provide [ ]  Can’t provide [ ]  I don’t know

**2、Complete PK detection method:**

[ ]  Can provide ( methodology summary) [ ]  Can’t provide [ ]  I don’t know

**3、Whether to collect tissues and organs\*:**

[ ]  Yes  [ ]  No [ ]  I don’t know

**4、Other detection (immunogenicity, pathological detection, etc.) :**

[ ]  Yes  [ ]  No [ ]  I don’t know

**5、PK results in discovery period:**

 (Animal species, Pharmacokinetic parameters…)

**6、Other requirement:**

**If you need Toxicity study, please fill in this information form (\* is required):**

**1、Complete bioanalysis method\*:**

[ ]  Can provide [ ]  Can’t provide [ ]  I don’t know

**2、Known toxic organ or toxic reaction\*:**

[ ]  Yes  [ ]  No [ ]  I don’t know

**3、Tox results in discovery period:**

 (Dose concentration, frequency, pathological index, etc., or Reference…)

**4、Other requirement:**