

## Questionnaire – Development of a monoclonal antibody based pharmacokinetic assay against a protein

Please fill out this form as a prerequisite for planning and specifying the major steps of the respective project.

It will also be used as the basis for quotation and further discussion of project details.

All information provided including the client information at the end of this questionnaire will be treated strictly confidential. A nondisclosure agreement can be signed upon request.

### 1. Antigen Information - Protein

Protein name: \_\_\_\_\_

Protein family: \_\_\_\_\_

Protein function: \_\_\_\_\_

Origin of protein:

Bacterium

Virus

Plant

Animal

Other, please specify: \_\_\_\_\_

Please specify species information: \_\_\_\_\_

**Biosafety level:**                      **1**                      **2**

For BSL2 (biosafety level 2 according to Biological Agents Ordinance [https://www.gesetze-im-internet.de/englisch\\_biostoffv/englisch\\_biostoffv.pdf](https://www.gesetze-im-internet.de/englisch_biostoffv/englisch_biostoffv.pdf) please provide risk analysis.

If samples submitted are GMO, please attach Formblatt Z or relevant documentation. The final risk assessment and security level for GMO organisms will be finalized by Biogenes in accordance with the German law since regional differences may occur. (Genetic Engineering Safety Ordinance – GenTSV) <https://www.bmleh.de/SharedDocs/Gesetzestexte/EN/GenTSV-E-en.html>

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In case of recombinantly expressed protein, is the construct designed as a fusion protein?

Yes

No

If yes, which tag has been used as fusion partner:

His-Tag, please add sequence of the tag: \_\_\_\_\_

GST-Tag, please add sequence of the tag: \_\_\_\_\_

Other, please specify tag sequence and provide molecular weight [kDa]: \_\_\_\_\_

Estimated molecular weight of the total antigen protein [kDa]: \_\_\_\_\_

Purity [%]: \_\_\_\_\_

Protein condition:

Native

Denatured

Is the protein available in buffer?

Yes

No

If yes, please answer the following questions:

Availability of the protein in buffer:

Soluble

Precipitated

Does the buffer contain a preservative? (BioGenes does not recommend the use of preservatives)

No

Yes, please specify: \_\_\_\_\_

Homology to mouse:

Yes

No

If yes, please indicate the degree of homology:

>70%

<70%

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### 2. Antibody Development

Should cross-reactivity testing be included?

Yes

No

I am not sure yet

If yes, please indicate the kind of selection:

Positive

Negative

Cross-reactivity test for characterization only

Are cross-reactants (commercially) available?

Yes

No

Name: \_\_\_\_\_

Purity [%]: \_\_\_\_\_

Molecular weight [kDa]: \_\_\_\_\_

Cross-reactants are available in buffer:

Soluble

Precipitated

Is further information about cross-reactants available (please provide)?

\_\_\_\_\_

**Biosafety level:**

**1**

**2**

**If > BSL1, please provide a proper risk assessment.**

If the cross-reactant is a genetically modified organism, please specify:

\_\_\_\_\_

\_\_\_\_\_

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### 3. Antibodies to be used in

Western Blot	Yes	No	I am not sure yet
ELISA	Yes	No	I am not sure yet
Immunohistochemistry	Yes	No	I am not sure yet
Immunofluorescence assay (IFA)	Yes	No	I am not sure yet
Immunoassay development	Yes	No	I am not sure yet

Other, please specify: \_\_\_\_\_

### 4. Preparation of cell culture supernatant for testing

Should preservatives be added prior to cell culture supernatant shipment?

No                      Yes, please add the following:

NaN3                      0.2 µm filtrated                      ProClin                      Not filtrated

Other, please specify: \_\_\_\_\_

### 5. Information about the intended pharmacokinetic assay

Please estimate the required detection range of the ELISA:

\_\_\_\_\_

Please estimate the expected shelf life of the assay and the number of tests (per year):

\_\_\_\_\_

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### Did you already contact a CRO? If yes, please provide details

An early contact with CRO is necessary in order to discuss specific requirements and plans regarding the assay. If no CRO has been selected yet, BioGenes recommends its preferred partner for these services FyonBio, Berlin/Germany, [www.fyonibio.com](http://www.fyonibio.com).

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### Are serum samples already available (i.e., from early stages of clinical trials)?

Serum samples are necessary for the characterization and selection of the antibody pairs during assay development. If no serum samples are available, please provide information about patient specification (i.e., gender, age, disease, additional medication). BioGenes will purchase sera with the respective specifications and spike them with the drug.

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## 6. Further assay information

Establishment and implementation of an assay control sample

Yes

No

I am not sure yet

## 7. Antibody Sequencing

Sequencing of hybridoma cells at BioGenes:

Yes

No

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### 8. Please provide additional information on:

Planned timelines: \_\_\_\_\_

Payment planned directly or via a purchasing platform (e.g. Scientist.com):

\_\_\_\_\_

How did you find out about BioGenes? \_\_\_\_\_

Other information not previously covered: \_\_\_\_\_

### Client Information:

Company/Institution name: \_\_\_\_\_

Contact person: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Phone: \_\_\_\_\_

Email: \_\_\_\_\_

Date: \_\_\_\_\_