

Questionnaire – Development of a monoclonal antibody based pharmacokinetic assay for a therapeutic antibody

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.

1.1 Antigen Information - Antibody

Name: _____

Isotype and subclass: _____

Antibody is available as:

Whole molecule

F(ab')₂-Fragment

Fab-Fragment

scFv/Fv-Fragment

Other, please specify: _____

Fragmentation requested?

Fab-Fragment

F(ab')₂-Fragment

No

I am not sure yet, please provide advise.

The antibody or functional parts thereof are derived from which host species:

Human

Other, please specify: _____

Other modification of the antibody:

Humanized

Chimeric, please specify: _____

Antibody-drug-conjugate

Other, please specify: _____

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1.2 Antibody-Drug-Conjugate Information (if applicable)

Please specify the structure of the conjugate (hapten), including the linker, or specify the group that is used for conjugation to the antibody, respectively:

Please provide additional information on structure or characterization of the drug substance if available:

Is the drug substance/the antigen a cell toxin?

No

Yes, please specify: _____

1.3 Antibody Preparation

Is the antibody or the antibody-drug-conjugate 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 preservative: _____

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

For BSL2 (biosafety level 2 according to Biological Agents Ordinance 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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2.2 Characterization of monoclonal antibodies

Is the identification of monoclonal anti-idiotypic antibodies, which recognize the antibody binding site, requested? (Competitive ELISA with original antigen)

Yes

No

Are antibodies against the selected antigen commercially available?

Yes, please specify: _____

No

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: _____

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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):

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.

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.

6. Further assay information

Establishment and implementation of an assay control sample

Yes

No

I am not sure yet

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7. 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: _____