

## Questionnaire – Development of a polyclonal antibody based immunogenicity 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')<sub>2</sub>-Fragment

Fab-Fragment

scFv/Fv-Fragment

Fragmentation requested?

No

I am not sure yet, please provide advise.

Fab-Fragment

F(ab')<sub>2</sub>-Fragment

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

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:

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

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Is the drug substance/the antigen a cell toxin?

No                      Yes, please specify: \_\_\_\_\_

Is the antibody, or the antibody-drug-conjugate available in buffer?

No                      Yes

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. Antibody Development

Immunization protocol for:

Rabbit (recommended)                      Goat

Immunization with:

Whole molecule                                  F(ab')<sub>2</sub>-Fragment

Fab-Fragment                                      scFv/Fv-Fragment

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

### 3. Preparation of polyclonal anti-idiotypic antibodies or antiserum

Should preservatives be added prior to polyclonal anti-idiotypic antibody or antiserum shipment?

No                                      Yes, please add the following:

NaN<sub>3</sub>                      0.2 µm filtrated                      ProClin                      Not filtrated

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

Should cross-reactivity testing be included?

Yes                      No                      I am not sure yet

If yes, please indicate kind of selection:

Positive                      Negative                      Cross-reactivity test for characterization only

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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)?

\_\_\_\_\_

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

Yes

No

Are there antibodies against the selected antigen (commercially) available?

\_\_\_\_\_

### 4. Information about the intended immunogenicity 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 characterisation 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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### 5. 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: \_\_\_\_\_