

# Influence of Antibody Attributes on Clinical Success – A Technology and Coporate Benchmark Analysis

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## Abstracts

### How do antibody characteristics impact clinical success?

The analytical report 'Influence of Antibody Attributes on Clinical Success – A Technology and Coporate Benchmark Analysis' evaluates the impact of a number of antibody attributes on the success rate of antibodies in clinical development. Among the antibody attributes studied in this investigation are antibody generation technology, animal species of the parental antibody, antibody format, immunoglobulin class and isotype, target, and therapeutic area. Information from more than 500 naked recombinant monoclonal antibodies was used for this research. Antibodies which failed in clinical development were further analyzed for the reason of failure and phase in which they were discontinued. Biotech and pharmaceutical companies with a significant R&D portfolio of therapeutic antibodies were benchmarked for their antibody success rate in development and the underlying antibody attributes contributing to success.

Specific antibody attributes evaluated for their influence on success in clinical development in this research study are:

In vitro antibody generation technologies: display technologies from CAT, Dyax, Morphosys, BioInvent, Domantis, Genentech, others;

In vivo antibody generation technologies: chimeric, primatized, nanobodies, deimmunized, human engineered, humaneered, humanized, XenoMouse, HuMab mouse, KM mouse, VelocImmune mouse, human B-cell derived;

Animal species of parental wild-type antibody: mouse, rat, rabbit, hamster, cynomolgus monkey, camelid;

Target;

Immunoglobulin(Ig) class;

IgG isotype;

Therapeutic area of lead indication.

When discovering a new monoclonal antibody, researchers have a number of choices to make regarding antibody generation technologies as well as antibody format and immunoglobulin isotype among other attributes. One of the basic controversies in selecting the antibody generation technology is the question whether antibodies generated in vitro by display technologies are really equivalent to those generated in vivo by a competent immune system.

### **Typical questions in antibody R&D are:**

When selecting an in vivo system for antibody generation, are conventional in vivo systems with an animal immune system and subsequent chimerization or humanization creating the same as „modern“ transgenic animals?

Are full length antibodies more successful than modern engineered nanobodies, scFv molecules or even domain antibodies?

Do companies have different success rates in their antibody development portfolio?

And, if yes, are they using different technologies than their peers which could explain the difference?

Is there a different success rate of antibodies against the same target based on generation technologies or other attributes?

Are there therapeutic areas with higher likelihood of successful development of antibodies than others?

What are the main reasons for antibody failure in clinical development?

In which phase do antibodies typically fail?

This analytical report will give you answers for many of these questions. The results of the analysis show

whether and how antibody generation technologies differently impact clinical success;

why and when antibodies fail;

how target selection influences clinical success;

if antibody format, class and isotype is relevant for development success;

the antibody success rate of therapeutic areas;

which companies are the most successful and which antibody attributes they prefer.

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