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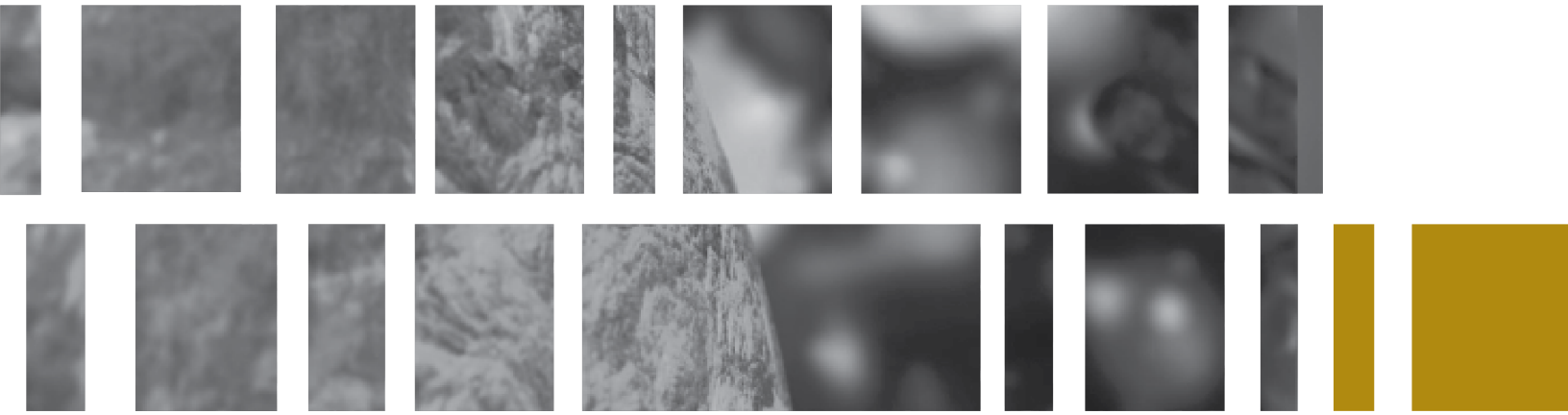

AN INDUSTRY BRIEF FROM INSTITUTE@PRECISION

Journey of a Therapeutic Antibody: From Preclinical to Clinical Proof of Concept

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Introduction

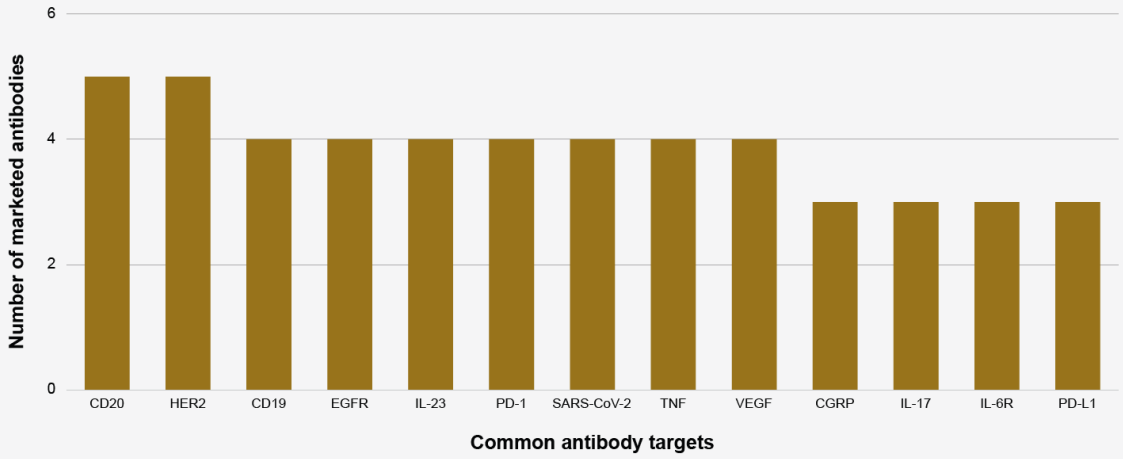
Therapeutic antibodies are on the ascendancy, driven by a significant evolution in antibody engineering and an expanding market. Antibodies have become the fastest-growing class of biologic drugs and are used for treating a wide range of indications, from oncology and immunology to infectious and hematological diseases.1 Since the first approval in 1986, there are now more than 165 antibody-based drugs, either approved or under regulatory review.

In this eBook, we explore the journey of a therapeutic antibody in early development, highlighting the key assays on the critical path from preclinical to clinical proof of concept. Along the way, we also share real-life case studies demonstrating the challenges and opportunities of developing, validating, and implementing robust assays.

Overview of Therapeutic Antibodies

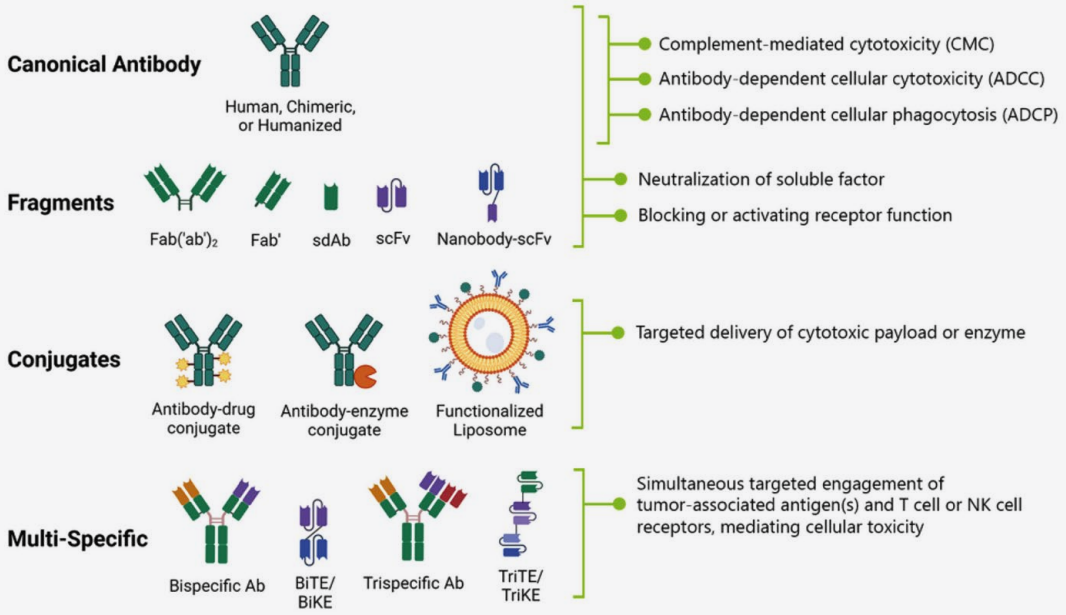
Therapeutic antibodies have a broad range of targets, including checkpoint or co-stimulatory markers, cytokines, growth factors, and immune cell markers (see Figure 1).

Figure 1. Marketed antibodies by target



These drugs also come in a variety of configurations, from monoclonal antibodies and multi-specific antibodies to antibody fragments and antibody-drug conjugates (ADCs) (see Figure 2).

Figure 2. Variety of therapeutic antibodies and their mechanisms of action[3]



Among the antibodies that have been approved, most are in immunoglobulin G (IgG) format. While antibodies are most commonly used in the treatment of cancer, autoimmunity, and chronic inflammatory disease, their applications are being extended to infectious diseases, hematology, neurology, ophthalmology, metabolic conditions, musculoskeletal diseases, and transplantation.[2] Development of a therapeutic antibody typically arises from a hypothesis for intervention in the pathobiology of a disease.

The journey from discovery of a promising antibody target to achievement of clinical proof of concept is a complex, multifaceted process that requires the integration of scientific knowledge, rigorous testing, and technological innovation (see Figure 3). Here we guide you through the fundamental stages of early development, providing insight into how therapeutic antibody candidates progress from preclinical testing to early phase clinical trials.

Figure 3. Early development path for a novel therapeutic antibody

Preclinical Target and Biomarker Validation

Target and biomarker validation is fundamental to successful therapeutic antibody development. It is critical to understand both the prevalence of the target in disease and the relationship between target expression and disease pathophysiology.

Understanding Target Expression and Localization

Target gene expression can be quantified in different disease cohorts and non-diseased controls using quantitative real-time reverse-transcription polymerase chain reaction (qRT-PCR).

Gene localization can be performed using in situ hybridization (ISH) and protein localization can be evaluated using immunohistochemistry (IHC) or multiplex immunofluorescence (mIF).

Of note, the use of human tissue is an essential approach for validating findings from animal models or cell lines and for understanding the expected ranges of target expression in the clinical population of interest.

Characterizing Novel Therapeutics

Characterization of a novel therapeutic involves a comprehensive analysis of its properties, structure, and function. For therapeutic antibodies, characterization often involves:

- Analyzing the structure of the antibody.
- Assessing its binding affinity and specificity to the target antigen.
- Evaluating its biological activity through cell culture-based assays.
- Determining its stability and potential for aggregation.
- Identifying and quantifying any post-translational modifications.

Case Study

Development and validation of an assay for screening anti-TNFα biosimilars

A pharmaceutical company was seeking a specialized cell-based assay for examining cytokine secretion by synovial fibroblasts from patients with rheumatoid arthritis as a screening tool for large molecule anti-TNFα biosimilars.

Precision for Medicine sourced the primary human cells and developed a 2D assay for measuring the secretion of interleukin (IL)-6. Following the relevant assay validation guidance, this cell-based assay was validated for linearity and range, relative potency, parallelism, specificity, and both intra- and inter-assay precision. The sponsor was able to use the assay for screening novel anti-TNFα molecules for relative potency versus adalimumab (Humira®) (see Figure 4).

Initially developed for screening large molecule anti-TNFα biosimilars, this assay has now also been applied to screening small molecule anti-TNFα compounds.

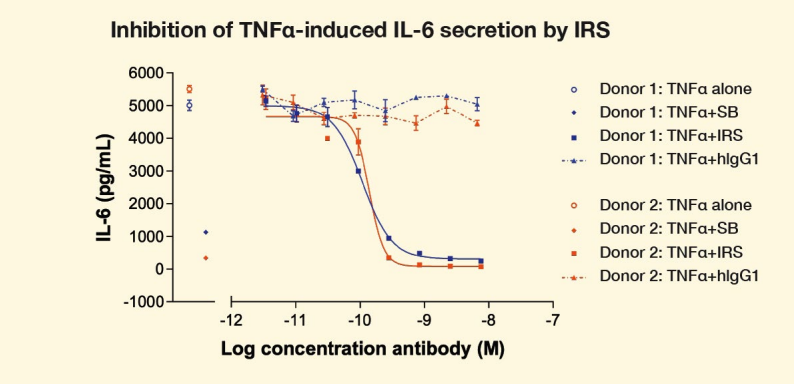


Figure 4. Inhibition of TNFα-induced IL-6 secretion

Assessing Disposition and Safety

The process of assessing the disposition and safety of a therapeutic antibody involves rigorous evaluation of its behavior in the body and its potential risks. This evaluation includes:

- Pharmacokinetic analysis of the antibody's absorption, tissue distribution, metabolism, and excretion.
- Immunogenicity testing to evaluate the potential of eliciting an undesirable immune response.
- Toxicity studies to identify potential adverse effects.

Biodistribution is a key part of the assessment of drug disposition. IHC is one of the techniques that can be used to identify the presence of biotherapeutics in tissues post-treatment. These biodistribution assays enable researchers to identify and confirm target organs and, therefore, can be used to support efficacy and safety.

Many of the preclinical investigations required for an investigational new drug (IND) application or clinical trial application (CTA) are intended to minimize the risk of harm in first-in-human studies. For therapeutic antibodies and antibody-like molecules, preclinical tissue cross-reactivity (TCR) studies have become an essential tool for not only identifying off-target binding, but also detecting previously unknown sites of on-target binding.

The presence of off-target therapeutic antibody binding in frozen ex vivo tissues provides insight into potential in vivo organ toxicity, while identification of new sites of on-target binding offers the possibility of indication expansion.

For regulatory submissions, TCR studies must be conducted under good laboratory practice (GLP) according to the published guidance.[4,5]

Key Considerations for Designing a TCR Study

One of the most important aspects of developing a TCR study is the optimization of the IHC protocol to be used. Therapeutic antibodies are drug molecules and are not inherently designed to be IHC reagents, posing technical challenges to assay development.

It is also important to keep in mind that a favorable dataset for a TCR study is a broadly negative result indicating no off-target binding. Therefore, to rule out any false negative results, it is critical that the assay is specific and robust prior to evaluation of the required test tissue panel.

Partnering With the Right Preclinical Testing Provider

Performing TCR assays on well-characterized, high-quality specimens is essential for generating the robust data needed to manage development risk and support regulatory submissions.

The right preclinical testing provider should have access to the human tissue types recommended by the FDA and EMA for testing and the specialty lab capabilities needed to support development and conduct of robust TCR studies under both non-GLP and GLP conditions (see Table 1).

Adrenal gland	Ileum	Prostate
Bladder	Kidney - glomerulus and tubule	Skeletal muscle
Blood cells	Liver	Skin
Blood vessel endothelium	Lung - bronchus and parenchyma	Spinal cord
Bone marrow	Lymph node	Spleen
Breast	Ovary	Stomach
Cerebellum	Pancreas	Testis
Cerebral cortex	Parethyroid gland	Thymus
Colon	Parotid salivery gland	Thyroid gland
Eye	Peripheral nerve	Tonsil
Fallopian tube	Pituitary gland	Ureter
Heart	Placenta	Uterus - cervix and endometrium

Table 1. Tissue types required for TCR testing

Early Clinical Development

In the early stages of clinical development, continued evaluation of a candidate therapeutic antibody focuses on certain core clinical assessments and exploratory biomarker studies.

Core Clinical Assessments

Core clinical assessments for therapeutic antibodies include pharmacokinetic (PK) assays and immunogenicity testing. Typically, these assays are run in serum or plasma matrices and are developed using either enzyme-linked immunosorbent assay (ELISA) or electrochemiluminescence immunoassay (ECLIA) on the MesoScale Discovery (MSD) platform. The MSD platform can offer the advantage of better assay sensitivity.

Immunogenicity assays include anti-drug antibody (ADA) assays, neutralizing antibody (NAb) assays, and drug-specific immunoglobulin E (IgE) and complement testing.

Case Study

Validating an Electrochemiluminescent Immunoassay

In partnership with Precision for Medicine, a sponsor developed a noncompetitive ECLIA for quantifying a biologically active fusion protein in human serum. This assay employs a rat monoclonal antibody for specific capture of the fusion protein via its intact C-terminus. Bound protein is detected using a chicken antibody conjugate that is specific to the core region of the fusion protein and does not cross-react with the C-terminus. In order to support ongoing PK assessments in patients with non-alcoholic steatohepatitis (NASH), the sponsor needed to validate this assay.

Reliable quantification of the biologically active fusion protein at concentrations as low as 29 ng/mL was achieved, demonstrating that the assay had suitable analytic performance to support PK assessments in healthy adults and patients with NASH. The study also showed that the PK profile of the fusion protein was dose proportional and similar between patients with moderate-to-advanced fibrosis and those with compensated cirrhosis in the 50 mg dose group (see Figure 5).

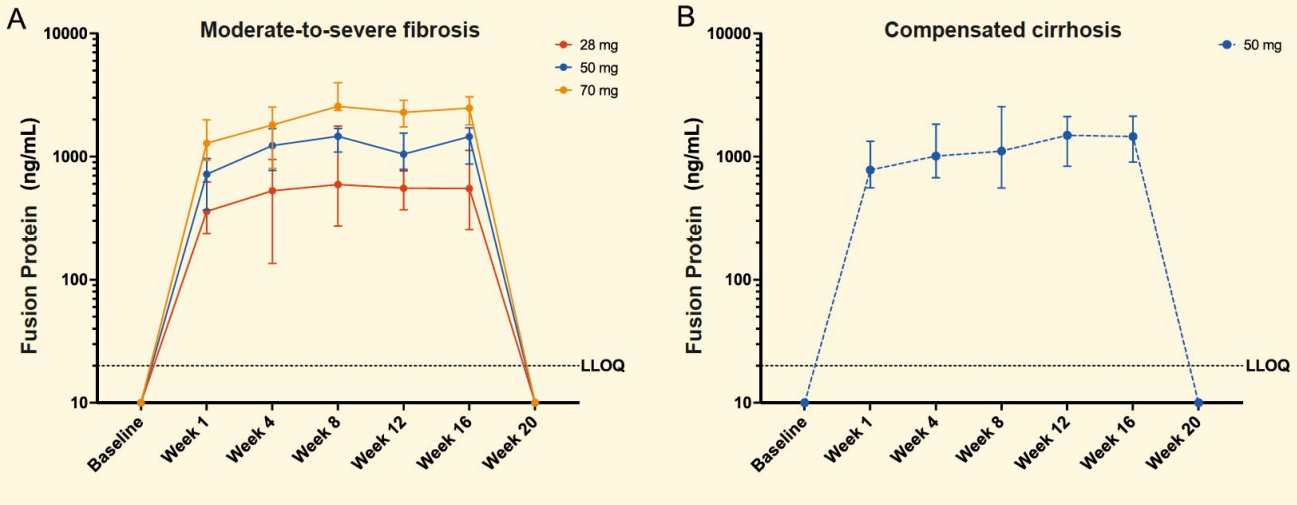


Figure 5. Biologically active fusion protein concentrations over 16 weeks of dosing representing trough concentrations in (A) moderate-to-severe fibrosis and (B) compensated cirrhosis. Fusion protein concentration was measured prior to dose administration at the end of the study week indicated and data are presented as median ± 95% confidence interval6 LLOQ, lower limit of quantification.

Exploratory Biomarkers

Exploratory biomarkers offer the opportunity to obtain additional information about mechanism of action (MOA) and target engagement to support proof of concept. In early phase studies, exploratory biomarkers can also be used to support PK- and safety-driven dosing decisions that take the molecule into the next phase of clinical development. A variety of assays can be used for pharmacodynamic (PD) assessments of exploratory biomarkers, including:

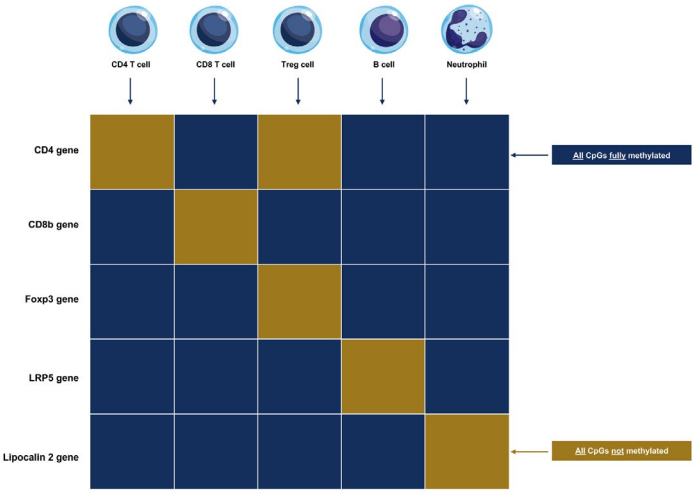
- Immunophenotyping using flow cytometry or epigenetic immune cell monitoring
- Receptor occupancy using flow cytometry
- Protein or cytokine analysis using MSD, ELISA, or automated Western blotting to assess a biomarker involved in the drug's MOA
- Tissue analysis using immunohistochemistry (IHC) for single or multiple markers

Immunophenotyping

Flow cytometry is a powerful tool for immunophenotyping in early phase studies due to its multiplexing capability. It can be performed on either whole blood or isolated peripheral blood mononuclear cells (PBMCs) and can examine a combination of many different surface, intracellular, or intranuclear markers at the single-cell level. In addition to providing information on immune cell subsets and activation states, flow cytometry can be used to evaluate absolute cell counts and intracellular cytokine secretion. While large, complex panels are useful in the early exploratory phase, it is important to identify key markers and utilize smaller, more well-defined panels in the later phases of clinical development.

In addition to flow cytometry, epigenetic immunophenotyping has emerged as a complementary and practical alternative for immune cell monitoring. Precision for Medicine's proprietary Epiontis ID® technology requires only a small sample and does not need viable cells, eliminating the need for PBMC processing or cryopreservation of cells. This technique can be applied to frozen blood, formalin-fixed paraffin-embedded (FFPE) samples, cell pellets, or dried blood spots to measure up to 37 immune cell types, including B and T cells or subsets of T cells such as memory CD4 T cells (see Figure 6). This approach allows for the generation of immunophenotyping data from clinical samples collected at remote sites, where isolating PBMCs from fresh blood is not feasible. As a PCR based assay, it is also scalable for later-phase clinical trials. To date, over 72,000 samples have been analyzed using this method across 118 clinical trials.

Figure 6. Using epigenetic patterns in marker regions to identify distinct cell types



Epigenetic marker regions are often, but not always, identical with the main flow cytometry target. Importantly, Epiontis ID has been shown to correlate well with flow cytometry (see Figure 7).

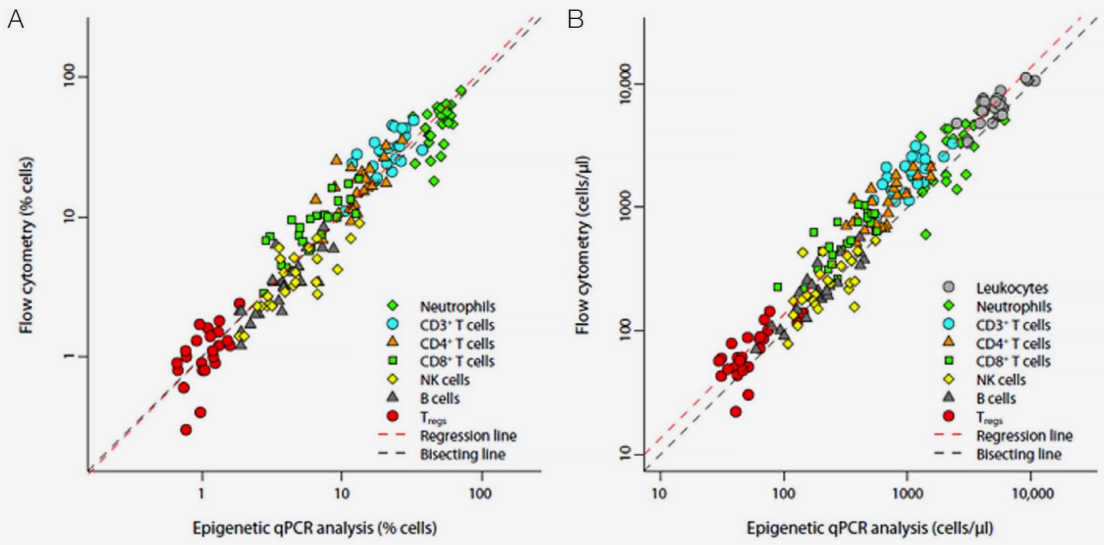


Figure 7. Comparison of immune cell quantification by flow cytometry (y axis) and epigenetic qPCR (x axis). (A) Relative immune cell counts shown as a percentage of total leukocytes. (B) Absolute immune cell counts shown as a cell number per microliter of whole blood. The regression line is depicted in red as computed from all data points, and the black line indicates the bisectrix[8]

Epiontis ID® assays have been fully validated under ISO 17025 and can be customized into panels that are specific to the scientific question being asked (see Table 2).

Table 2. Validated assays for Epiontis ID

T Lymphocytes	Other Immune Cells	Exhaustion,Activation, And Migration Markers	Other Cell Types (Fibrocytes)
CD3 T Cells	B Cells	PD1+ Cells	Col1a1+ Cells
CD4 T Cells	NK Cells	TIGIT+ Cells	PDGFRB+ Cells
CD8 T Cells	Neutrophils	CTLA4+ Cells	
Regulatory T Cells	Eosinophils	LAG3+ Cells	
Th17 Cells	Basophils	CXCR3+ Cells	
TFH Cells	Monocytes	Granulysin+ Cells	
Gamma Delta T Cells	NC Monocytes	CCR7+ Cells	
GATA3+ Cells	Monocytic MDSC	IL6R+ Cells	
CD4 Memory T Cells	Plasmacytoid DC	CCR6+ Cells	
CD8 Naive T Cells	Naive B Cells	CRTH2+ Cells	
	Memory B Cells	S1PR1+ Cells	
	IgM+ B Cells	S1PR5+ Cells	
		Integrin Alpha 4+ Cells	

Receptor Occupancy

Often used to generate pharmacodynamic (PD) biomarker data in preclinical and clinical studies, receptor occupancy (RO) assays are designed to quantify binding of drugs to cell surface targets. In therapeutic antibody development, RO assays provide essential information about the interactions between the antibody and its target, helping to elucidate MOA, predict therapeutic efficacy, and inform dosing strategies. RO assays can be used for:

- Determining whether the drug is effectively reaching and engaging its intended target
- Assessing competition with endogenous ligands for the same receptor
- Providing insights into the biological pathways affected by the drug
- Evaluating whether level of receptor occupancy correlates with clinical responses
- Optimizing the dose of the therapeutic antibody to achieve a desired level of target engagement, thus balancing efficacy and safety
- Monitoring treatment response over time
- Identifying mechanisms of resistance—such as receptor mutation, downregulation, or internalization—that may reduce receptor occupancy

Flow cytometry-based RO assays quantify the occupancy of drug to its target receptor by measuring the levels of occupied, free, and total receptors at the single cell level after therapeutic antibody treatment (see Figure 8). Drug-bound occupied receptors are detected using an anti-idiotype or secondary antibody against the therapeutic antibody. Free receptors are detected using either fluorescently-conjugated therapeutic drug or a competing antibody. Total receptors are detected with a non-competing antibody. If a non-competing antibody is not available, the total receptor assay can be performed in a separate tube with saturating drug and total receptors can be detected with either labelled drug, a secondary antibody against the therapeutic antibody, or by an anti-idiotype antibody.

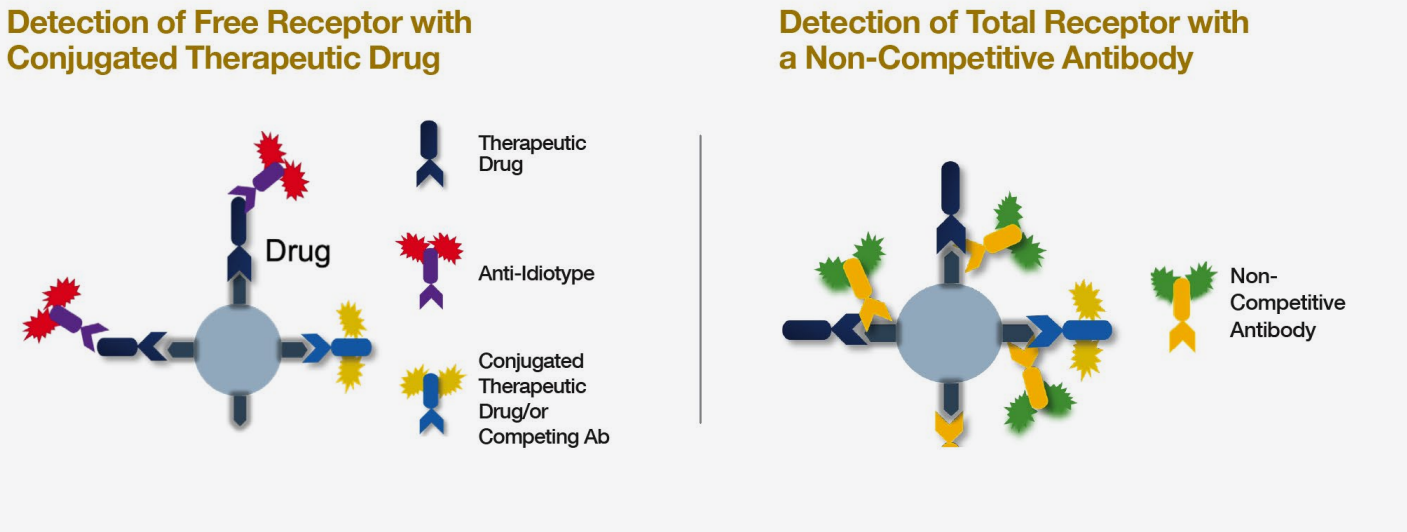


Figure 8. Schematic of typical RO assay

Case Study

Receptor Occupancy Assay

Precision for Medicine developed and validated a 10-color flow cytometry assay to assess the engagement and modulation of cell-surface CD6 on T cells in both fresh (WB) and fixed whole blood (ST/WB) samples. This assay was designed to monitor target engagement and changes in receptor levels for pharmacokinetic (PK)/pharmacodynamic (PD) modeling in patients treated with an immuno-modulatory therapy for autoimmune and inflammatory diseases (see Figure 9).

Validation parameters included intra-assay, inter-assay, and inter-operator precision, and post-staining stability. At a drug dose of 50 µg/mL, the CD6 percentage receptor occupancy (RO) detected was ≤87% in fresh whole blood CD4 T cells and ≤76% in CD8 T cells, while in fixed whole blood, it was ≤84% in CD4 T cells and ≤49% in CD8 T cells. These assays were validated to be both sensitive and selective in assessing CD6 target engagement and modulation as a PD marker in conditions such as graft-versus-host disease and systemic lupus erythematosus. (see Figure 10).

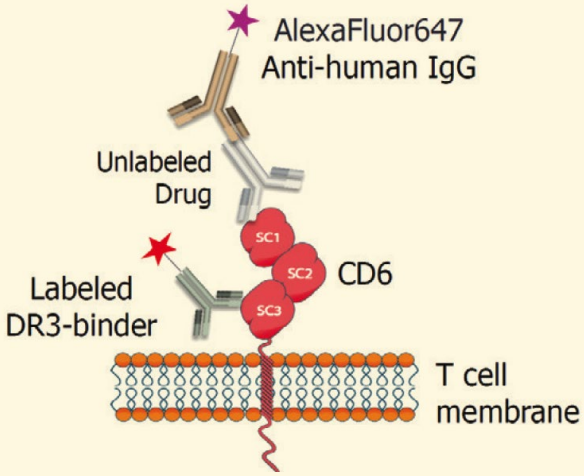


Figure 9. Receptor Occupancy of CD6. Anti-human IgG1 antibody detects drug-bound CD6. A non-competing anti-human distal receptor CD6 antibody to the drug detects total CD6 on the cell surface, and an antibody cocktail for cell surface markers identifies T cell subsets.

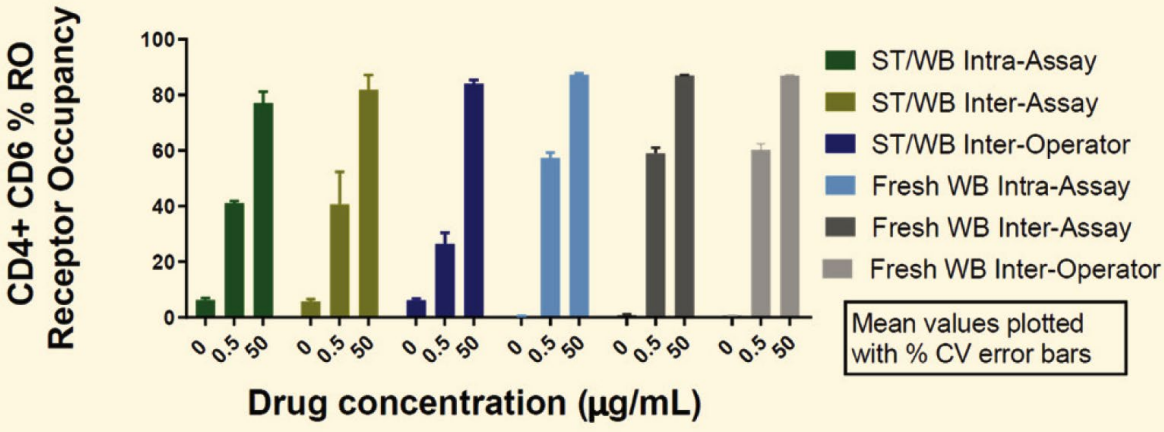


Figure 10. CD4 T cell CD6 Receptor Occupancy Validation. Fresh whole blood was treated with drug, and samples fixed and stabilized using SMARTTM tube's proteomic stabilizer and stored at -80°C prior to testing. Different donors were used for fresh whole blood (fresh WB) and fixed (ST/WB) whole blood.

Protein and Cytokine Analysis

Protein and cytokine assays are indispensable, versatile tools for studying cellular biology, exploring the relationship of biomarker function in elucidating disease mechanisms and informing therapeutic development. Researchers who are planning to analyze or quantify proteins or cytokines as biomarkers in clinical trials should think carefully about how to translate preclinical assays into the clinical environment. Oftentimes—particularly in the exploratory clinical stages—researchers seek to gather as much data as possible to optimize the likelihood of detecting a signal in the later phases of clinical development.

Thus, it is common to perform multiplexed assays analyzing many protein and cytokine biomarkers in the early stages. However, it is essential to whittle down to the biomarker of highest interest for use in phase 2 and phase 3 studies. The selected biomarker should reflect the biology of the target drug interaction or the underlying disease mechanism. There are a range of different platforms that can be used for protein and cytokine analysis, each with characteristics that enable their application based on the analytical requirements of the assay (see Figure 11).

Figure 11. Comparison of platforms for protein and cytokine analysis




	ELISA	MesoScale (MSD)	Olink	Jess
Sensitivity	ng/mL - pg/mL	fg/mL	pg/mL	low pg
Dynamic Range	1-2 logs	3-4 logs	3-4 logs	3-4 logs
Multiplex Capabilities	1-3	10	45/92	1-3
Sample Volume	50 - 100 µL	25 µL	1 µL	3 µL
Use	All stages	All stages	All stages	All stages
Considerations	Single plex/Key Markers Not Covered In Higher Plex Platforms Breadth of Established Assays	Higher Plex Data Rich From Low Sample Input Breadth of Established Assays	Mid Plex Proteomics Panel Driven	Automated Western Improved Robustness & Sensitivity Customizable

- **ELISA** offers a variety of commercially available kits and does not require conjugation of antibody, so the time needed to develop an assay is relatively short. This approach generally provides the lowest analytical sensitivity, narrowest dynamic range, and least multiplexing capability, and has the largest sample volume requirement. It is often used where measurement of up to 3 analytes is required and sample volume is not limited.

- **MSD** can have a higher sensitivity and wider dynamic range compared to ELISA, and can provide multiplexing capability. MSD also offers validated off-the-shelf panels and a menu of established markers that can either be integrated into other panels or run separately, which adds flexibility. Due to their multiplexing capability, MSD assays are commonly used for cytokine profiling or discovery and profiling of novel biomarkers in early phase clinical trials. MSD offers the following platforms and kit types, which vary based on sensitivity, level of validation, and customizability:

  - S-PLEX is an assay platform with very high sensitivity (fg/mL), well-suited for low concentration biomarkers
  - V-PLEX offers pg/mL sensitivity and analytically validated single-plex and multiplex kits
  - R-PLEX and U-PLEX support customizable multiplex assays

Another advantage of MSD is the ability to develop an MSD-based assay from scratch or to convert an ELISA to an MSD assay.

- **Olink®**, a newer technology for ligand binding assays, is a powerful tool for early phase, protein biomarker profiling as an exploratory endpoint. Olink® requires a minimum of 15 to 21 targets and offers high throughput, wide dynamic range, high sensitivity, and very low sample volume requirement (1 µL). It is also compatible with a diversity of sample types from serum and plasma to dried blood spots, saliva, urine, fine needle biopsies, and other biological samples. Olink® offers various panels, including9:
  - Target 96 & 48 panels for targeted protein biomarker discovery
  - Flex, a made-to-order product customized with as many as 21 human proteins selected from ~200 pre-validated protein biomarkers
  - Focus, a custom panel of as many as 21 proteins from Olink®'s Target and Explore libraries Current limitations of Olink® technology are that it only measures samples with a single replicate and its software is not yet compliant with 21 CFR Part 11, so it is not suitable for regulated assays.
- **Jess™**, an automated Western blot system, combines traditional Western blot with ELISA. Jess separates proteins by size and can, for example, be applied to measuring both total and phosphorylated protein in the same sample as quickly as 3 hours. This technology also offers higher sensitivity in some tissue samples compared to other platforms. Biotechne, the manufacturer of Jess, does not provide off-the-shelf assay kits, but it does offer assay modules and a Simple Western Assay Kit Builder that allows researchers to design their own kits. This technology is restricted in terms of multiplexing compared to other platforms and its throughput is low, as per run sample numbers are 13 or 25, much lower than 96-well plate assays.

To select the most effective assay format for answering a specific scientific question, it is important to understand both the platforms available and the questions being asked. It is also essential to consider the availability of critical reagents and controls as well as potential downstream applications.

Tissue Analysis

Interrogation of tissue biomarkers is often necessary for providing insight into disease biology, investigating drug efficacy and safety or making diagnostic decisions regarding patient treatment. While tissue biopsies are invasive, they enable localized analysis of protein biomarkers and topographic investigation of disease- and drug-related changes. More recently, spatial analysis of multiple tissue biomarkers has been used to generate supporting or exploratory data during clinical development, especially in conditions with a core immune component, such as cancer, inflammatory, and autoimmune diseases.

IHC and mIF are frequently used for analysis of tissue biomarkers. The Akoya OpalTM platform can be used for quantitative mIF image analysis for of as many as 8 concurrent exploratory biomarkers. A common application of mIF is for investigation of the disease tissue microenvironment. For example, in immuno-oncology studies, this technology can be used to measure the extent of tumor infiltration to distinguish between cold and hot tumors and the changes in cellular localization and composition following treatment.

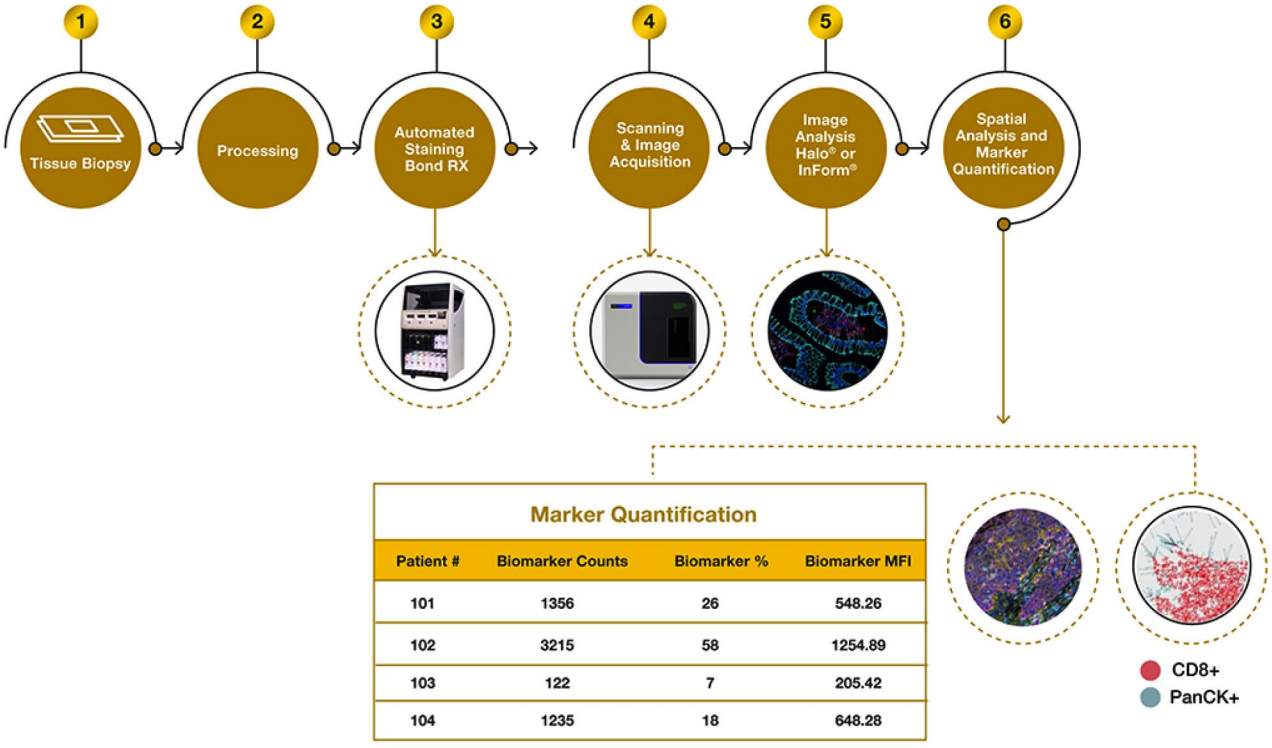


Figure 12. Multiplex immunofluorescence (mIF) workflow

When it comes to utilizing an IHC-based assay in clinical development, the level of assay qualification or validation required will depend on the application of the assay. While exploratory biomarker assays can be appropriately qualified to evaluate their robustness and reproducibility across indications, assays used to support patient enrollment or clinical decision making require a more rigorous analytical validation approach and follow the College of American Pathologists (CAP) or Clinical Laboratory Improvements Amendments (CLIA)-level requirements.[10,11]

Case Study

Tissue Biomarker Analysis with IHC for Patient Selection

Precision for Medicine developed and validated a custom IHC assay, reagent kit, and scoring index (SI) for assessing P-cadherin, a cellular adhesion protein that contributes to oncogenesis. The SI was based on the tumor area stained multiplied by the staining intensity. This assay was rolled out to 3 global phase 1 sites and study eligibility required an SI of greater than or equal to 4. Each site ran the IHC assays independently and used their own pathologists to do the analysis.

Precision for Medicine served as a central site, performing independent mass analysis of site results and finding a nearly 92% concordance in the results. This case study demonstrated the feasibility of developing an assay at a single center and running that assay at multiple sites across the globe.

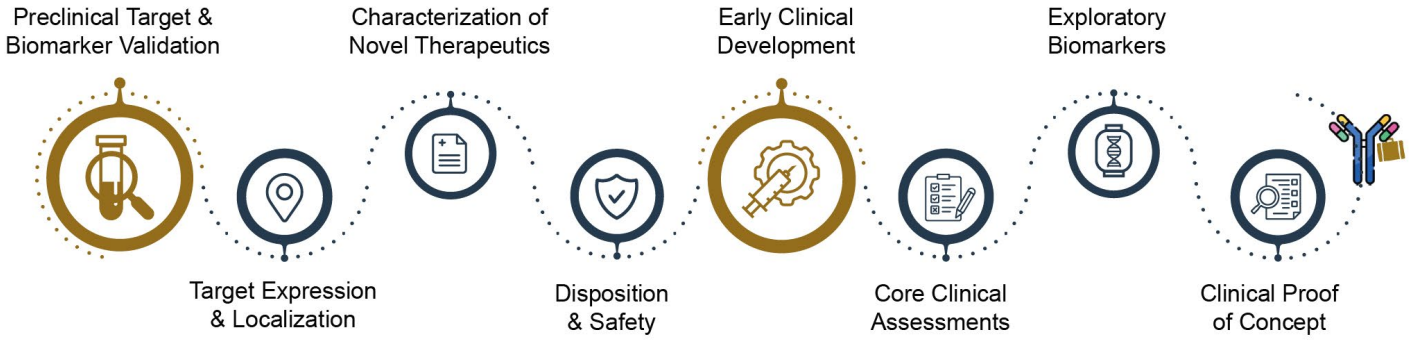
Conclusion

Development of a therapeutic antibody requires a significant investment of both time and capital. It is important to identify any potential issues with a novel drug as early in development as possible, both to minimize the potential for harm in clinical trials and to optimize the probability of success in late-stage studies.

Developing and implementing a rigorous approach to understanding target expression and localization, characterization of the therapeutic candidate, disposition and safety, pharmacokinetics, immunogenicity, mechanism of action, and target engagement can help developers accelerate the journey to clinical proof of concept.

Expert support can facilitate this entire process and ensure the success of a therapeutic antibody development program.

To learn more about how Precision for Medicine can support therapeutic antibody development, visit www.precisionformedicine.com.



Reference

1 Sharma P, et al. Therapeutic antibodies in medicine. *Molecules.* 2023;28(18):6438.

2 Carter PJ, Rajpal A. Designing antibodies as therapeutics. *Cell.* 2022;185(15):2789-2805.

3 BPS Bioscience. ADC and antibody-based cancer therapies. Accessed October 21, 2024. https://bpsbioscience.product_type_filter=5560&target_field=& research_areas=5966&assay_kit_format=&species_filter=.

4 U.S. Food and Drug Administration. *Guidance document: points to consider in the manufacture and testing of monoclonal antibody products for human use.* Published February 28, 1997. Accessed October 27, 2024. https://www.fda.gov/media/76798/download

5 European Medicines Agency. Guideline on development, production, characterization and specification for monoclonal antibodies and related products. Published July 21, 2016. Accessed October 27, 2024. https://www.ema.europa.eu/en/documents/scientific guideline-guideline-development-production-characterisation-and-specification-monoclonal-antibodies-and-related-products revision-1_en.pdf

6 Kinne AS, et al. Noncompetitive immunoassay optimized for pharmacokinetic assessments of biologically active efruxifermin. J Pharm Biomed Anal. 2023;232:115402.

7 U.S. Food and Drug Administration. M10 bioanalytical method validation and study sample analysis. Published November 2022. Accessed October 27, 2024. https://www.fda.gov/media/162903/download

8 Barron U, et al. Epigenetic immune cell counting in human blood samples for immunodiagnostics. Sci Transl Med. 2018;10(452):eaan3508.

9 Olink®, Accessed October 27, 2024. https://olink.com

10 College of American Pathologists. CAP Guidelines. Accessed October 27, 2024. https://www.cap.org/protocols-and-guidelines-cap-guidelines

11 Centers for Disease Control and Prevention. Clinical laboratory improvement amendments. Published September 11, 2024. Accessed October 27, 2024. https://www.cdc.gov/clia/php/about/index.html

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Dr. Rachel Owen is a global leader in immuno-oncology and infectious disease research, offering vast expertise in flow cytometry assay development, cell-based assays, and biomarker discovery. She is accustomed to both early and late phase clinical trials, making her a proficient strategist in translational studies. With her focus on providing valuable data for scientific discovery, she strengthens her partnerships in research. She earned her PhD in Immunology from University College London.

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