



Clinical development of advanced therapy medicinal products (ATMPs) requires, as part of the follow-up/inclusion of patients, the performance of specific analytical tests to follow biomarkers of interest or monitor the immunogenicity and shedding of the drug candidate.

As an expert in the evaluation of ATMPs, GenoSafe supports its customers from the inclusion of patients enrolled in **clinical** studies to their **analytical** follow-up, by implementing in-house methods or **validated** in compliance with the **FDA/ICH M10** recommendations.

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FOCUS 1

Titration of neutralizing antibodies / factors

Biotherapies such as vaccination seek to activate the immune system, while others, such as gene therapy or cell therapy, seek to prevent the activation of the immune system. It is therefore crucial to evaluate and characterize the immune response. GenoSafe offers tests to monitor the immune response in clinical studies.

Neutralization assays:

- ✓ Quantification of specific neutralizing antibodies/factors (e.g. AAV neutralizing antibodies)
- ✓ AAV NAb assays validated for many different serotypes (AAV2, AAV3, AAV5, AAV6, AAV8, AAV9 and customer specific serotypes)
- ✓ Custom development based on client needs

FOCUS 2

Titration of total antibodies / biomarkers

- ✓ Antibody detection/titration:
 - Antibodies arising from gene therapy vectors, transgene proteins, vaccines, etc
- ✓ Biomarker analysis:
 - Detection of a wide panel of pro-inflammatory cytokines and any kind of biomarkers of interest upon request
- ✓ Adaptability and customization
 - Generic and validated tests are already available
 - GenoSafe also performs custom method development to meet specific clients' requirements



FOCUS 3

Immune cell response

- ✓ Immune cell response profiling by FACS
- ✓ Immune cell response by ELISpot



FOCUS 4

Shedding / Expression in biopsies

GCP-compliant Biodissemination / Expression analyses:

- ✓ Biodissemination / Shedding: drug persistence in human excretions
- ✓ Expression of RNAs/proteins of interest in biopsied tissues and fluids

Our expertise includes:

- ✓ DNA/RNA extraction from various tissues/fluids
- ✓ qPCR / dPCR / RT-qPCR-based detection and quantification
- ✓ Advanced western-blotting methods for protein detection