Multicomponent drug modalities used in cell and gene therapies are complex, and understanding the multitude of factors that can induce immunogenic responses is critical to understanding the full immunogenicity risk of these compounds—and to controlling unwanted cellular and humoral responses.

Having worked on some of the very first cases of immunogenicity, BioAgilytix's scientists are experts in the assessment of cell-mediated and antibody-mediated immune responses to all biologicals including cell and gene therapeutics. We leverage our deep experience and successful regulatory track record in combination with a robust platform suite to perform a number of immunogenicity assessments for these therapeutic modalities, including non-regulated and regulated (GCLP) studies involving:

### Scientific Focus:
**IMMUNOGENICITY TESTING FOR CELL AND GENE THERAPIES**

<table>
<thead>
<tr>
<th>Type of Assessment</th>
<th>Key Platforms Used</th>
</tr>
</thead>
</table>
| **Immunogenicity to Vector—Humoral Response** | **Against Viral Vector:**  
- ELISA  
- MSD–ECL  
- Gyrolab  
**Against Lipid Nanoparticle:**  
- ELISA  
- MSD–ECL |
| **Immunogenicity to Vector—Cellular Response** | **ELISPOT**  
**Flow Cytometry** |

Expertise with both viral and non-viral delivery vehicles including adenovirus, AAV, lentivirus, lipid nanoparticles, cationic polymers, autologous and heterologous cells, etc.
There are a number of considerations to take into account when performing immunogenicity testing of cell and gene therapy compounds, as the nature of the vector, therapeutic protein, transgene, and route of administration can all cause distinct unwanted immune responses.

BioAgilytix's scientists will work collaboratively to help you choose the method to best fit your unique program parameters and will tailor our approach specifically to the therapeutic and immune response(s) being evaluated.

Not only do we provide a holistic evaluation of immunogenic profile, but will also help to develop strategies to circumvent issues caused by unwanted immune responses when possible.