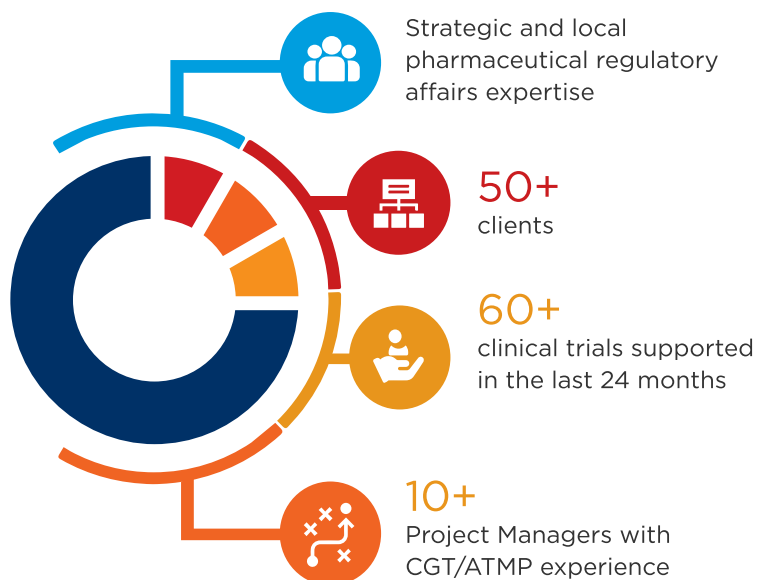


PrimeVigilance's CGT/ ATMP Services

Unique Benefits of PrimeVigilance's CGT/ATMP Services

PrimeVigilance stands at the forefront of the burgeoning Cell and Gene (CGT) / Advanced Therapy Medicinal Products (ATMP) sector, providing specialized and comprehensive support to organizations navigating this complex field. Our dedicated business unit harnesses the expertise from over 50 clients' research endeavors to ensure success in CGT/ATMP development.

With a foundation of experienced professionals, including Project Managers, Medics, Officers, Associates, and Regulatory experts—many of whom come with seasoned backgrounds in CGT/ATMP industries—we deliver nuanced pharmacovigilance strategies tailored to the unique demands of CGTs/ATMPs.



Recognizing the intricacies of post-licensure long-term follow-up studies and the rigorous medical assessment that CGT/ATMPs demand, we equip clients with the necessary tools and expertise to finesse their pharmacovigilance plans.

Our collaboration with Ergomed, our sister company, further enhances our capability to provide comprehensive services spanning Safety & Pharmacovigilance to full scope Clinical support.

Our offerings are designed to be flexible, providing as much or as little support as required to navigate the CGT/ATMP landscape efficiently.

Our value proposition

- 1 Expert Guidance**
Deep sector expertise through a team with firsthand CGT/ATMP and biotech experience.
- 2 Comprehensive Support**
From ICSR processing to full PV Project Management and regulatory navigation, we strive to align our professional resources, not only therapeutically, but with best fit in mind.
- 3 Custom Solutions**
Tailored services to meet the specific needs of CGT/ATMP development and lifecycle management.
- 4 Strategic Partnerships**
Enhanced support options through collaboration with Ergomed for integrated Safety, PV, and Clinical services

Our organization has worked on countless CGT/ATMP studies as outlined below, we are familiar with the types of patient profiles and SAE expectations and will therefore be able to apply lessons learned when managing Safety.

Therapeutic Area	Phases	# Studies supported by PVL
Oncology	I-IV	40
Endocrinology	I-III	32
Haematology	I-IV	15
Ophthalmology	I-III	12
Central Nervous System	I-III	5
Immunology	II-III	3
Cardiovascular	I-IIa	2
Gastroenterology	III	1
Musculoskeletal	II	1
Pulmonology	I/II	1
Other	I-III	15+

Post Authorisation

8+ products supporting ongoing Safety profile management

Tailored Solutions for Your Unique Needs (CGT/ATMP)

PrimeVigilance provides customized, scalable and cost-efficient solutions, with global technology systems that are customizable to meet bespoke customer needs.

We offer flexible delivery models with on-shore or off-shore resourcing and dedicated, hybrid and/or shared staffing service models.

Your project would take advantage of PrimeVigilance's in-house technology offerings & centralized content management and customer insights that drive operational efficiency (list of core services below)



Full ICSR processing (unique workflows that acknowledge the high regulatory scrutiny and need for completeness in first regulatory submission)



Benefit-Risk Management



Safety Systems & Reporting



Project Management



PSMF management and hosting



Medical Information Services (Full call centre)



Literature Surveillance



Pharmacoepidemiology



LCPPV & QPPV



Safety Medical Writing (DSUR, PBRER, RMP, etc.)



GVP audits and inspections and full support with client audit/inspections



Clinical Trial Safety, SMPs, SDEAs, Joint-Guides & Medical Monitoring



PV & Regulatory Strategy Consultancy

Why Choose PrimeVigilance for your CGT/ATMP Clinical Trial or Post Market Safety & PV



Innovative Solutions and Technology Investment

Advanced technology and offering cutting-edge solutions to meet evolving client needs



Customized and Flexible Approach

We are committed to adapting to meet your specific needs, offering full customisable solutions that make your client experience as smooth as possible. PrimeVigilance prides itself as a differentiator in this area, offering vast flexibility.



Data-Driven Insights

Leverage our insights & experience (lessons learned) to gain a better understanding of the most effective way to operationalise your project, leading to improved outcomes.



Patient-Centered Approach

Utilize our in-house professionals to directly engage your customer base through patient support and assistance programs.

Holistic. Scalable. Compliant.

Our unrivalled network is trusted across the industry, supported by experienced in-house QPPVs, regulatory professionals, and automation-ready infrastructure.



Ready to Partner? Contact Us Today!

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