

# Real Solutions to Challenges in Clinical Trials for Cell and Gene Therapy

Can stay alert to predators by sleeping with half of its brain at a time

Dolphin



Cmed is highly experienced in the management of cell and gene therapy clinical trials, whether in oncology, rare diseases or other therapeutic areas.

Operational challenges with cell and gene therapy trials

Cmed's experience and solutions

- Clinical trials are adaptive in nature
- Clinical trials are subject to rapid amendments



Complex Protocol Designs

#### Use multiple disciplines for clearer designs

- All Cmed Project Leaders have CGT experience
- Cross-functional expertise for operational efficiency

- Country specific laws and regulations
- Complex submissions and approval process



ATIMP Regulatory Processes

#### Rely on expert advice

- Strong experience in GMO and knowledge of country specific ethics requirements
- Proven experience in selection and management of applicable countries/sites

- Very complex collection and handling processes
- Reliable tracking between clinic and biolabs is essential



Manufacturing & Logistics

#### Plan ahead and adapt

- Cmed's processes allow for management of variations and specifics of therapies
- Advanced technology supports an end to end tracking process

- Data volumes per patient are high and complex due to multiple sources and techniques used
- Data deliveries are frequent for ongoing safety reviews

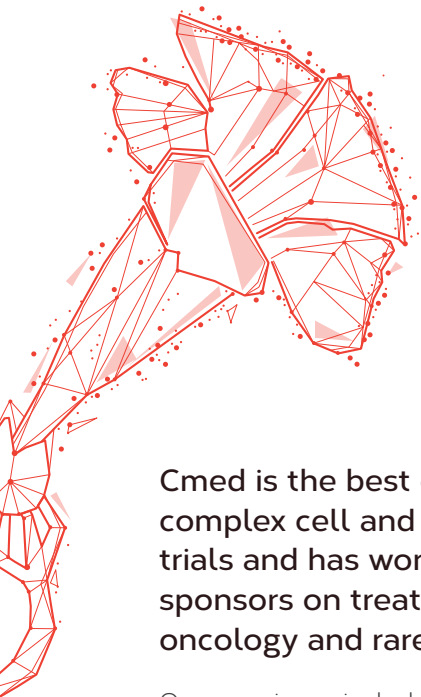


Data Availability & Technology

#### New generation technology

- The *encapsia* clinical data suite enables easy combination and integration of multiple data sources
- See all data in real time with interactive, actionable visualizations, improving safety monitoring

# Developed to fit your needs perfectly



### Hummingbird

Flexible, agile and highly adaptable: able to change direction almost instantly and even fly upside down

Cmed is the best choice to manage complex cell and gene therapy trials and has worked with multiple sponsors on treatments for oncology and rare diseases.

Our experience includes CAR-T cells, HSC, autologous Gamma-Delta T Lymphocytes, Adenovirus vector-based gene therapy etc.

Cmed understands the operationalisation of cell and gene therapy trials and has a proven track record of delivering quality data on time. Our teams, processes and technologies deliver success in the rapidly-changing trials common in cell and gene therapy.

### Cmed's experience in Cell and Gene Therapy



**26**

CELL & GENE THERAPY TRIALS



**100%**

ALL PROJECT LEADERS HAVE CGT EXPERTISE



**130+**

ONCOLOGY STUDIES DELIVERED



**100%**

OF CLINICAL STAFF HAVE ONCOLOGY EXPERIENCE



**10**

CAR-T TRIALS



**COMPLEX TRIAL DESIGN**

INCLUDING FIRST IN HUMAN, BASKET, ADAPTIVE AND ACCELERATED COHORTS.

Talk to us about your next clinical trial today:

Cmed Inc  
Morrisville, NC 27560  
United States  
T: +1 919 595 6900

Cmed Inc  
Cambridge, MA 02139  
United States  
T: +1 617 947 6681

Cmed Inc  
San Bruno, CA 94066  
United States  
T: +1 650 616 4291

Cmed Group Ltd  
Horsham  
United Kingdom  
T: +44 (0) 1403 755 050