Clinical Commercial SOLUTIONS GUIDE

GMP-Compliant Collections and Services

CGT CLINICAL

2023

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"Our success is measured by the success of your projects - we help guide you every step of the way, so you can get your therapies to the patients who need them."

- Cate Spears, Founder and CEO, CGT Global

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Success Starts at the Source

Eliona Kola, CGT Global Laboratory Process Development Scientist

From Product Development to Clinical and Commercial Production

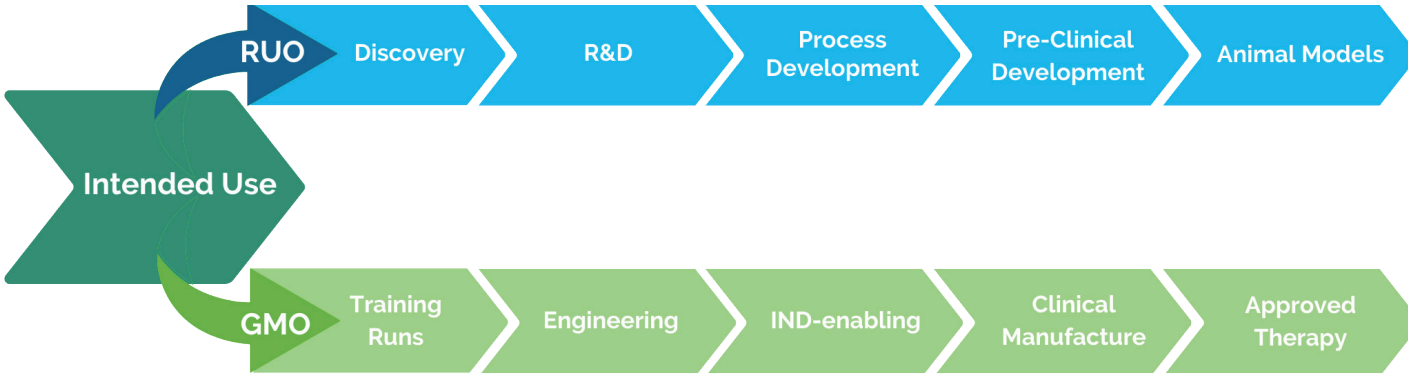
The mission of CGT Global is to expedite the advancement of lifesaving therapies, from research and development to final drug approval and beyond. With 13 years experience as a leading provider of healthy donor blood products and primary cells, CGT Global supports the cell and gene therapy industry from research and pre-clinical through clinical trials and commercialization. As more cell and gene therapy candidates are moving through the drug development process, the need for clinical-ready partners to support these projects is critical to success. CGT Global provides products, services, and targeted donor and patient recruitment from 4 privately owned locations nationwide and we are proud to offer our clients unparalleled flexibility, experience, partnership, cold chain logistics, and donor services to support your needs and improve patient outcomes around the globe.

Pre-Clinical (RUO) vs. Clinical (GMP) Products

Clients have different needs depending on their projects, and CGT consults with each client on an individual basis to determine compliance required based on the intended usage of our products. With more than a decade of experience as a leading provider of RUO and GMP healthy donor materials, CGT has unique expertise to provide customizable and flexible solutions to researchers and drug developers.

RUO VS GMP PRODUCTS	RUO	GMP
High Viability and Yield (15B TNC avg/ Leukopak)	✓	✓
Large Characterized Donor Pool (Coast-to-Coast)	✓	✓
CLIA Certified Laboratories	✓	✓
cGTP compliance	✓	✓
For Further Manufacture and Commercialization	✗	✓
GMP-compliant customizable documentation	✗	✓
Quality Assurance Batch Review & Release	✗	✓
FDA 21 CFR Part 1271 Donor Eligibility & Testing	✗	✓

CGT adheres to local and federal regulations for clinical GMP-compliant products. We ensure donor and patient eligibility is determined according to FDA 21 CFR Part 1271 subpart C., and donor testing is performed within 7 days prior to each collection. We offer customized capabilities to meet additional or international regulatory requirements such as EMA regulations by adding on additional infectious disease testing at multiple time points, client-specific documentation, or other services to fit your project needs. GMP-compliant products must follow extensive quality assurance oversight and documentation in accordance with the FDA and other regulatory bodies. CGT employs a rigorous document control and training procedure under a compliant Quality Management System (QMS) and has written procedures in place for the release of product, process improvement and corrective and preventative actions.



Donor Management Solutions

CGT donor during apheresis collection on Terumo Spectra Optia® machine

Coast-to-coast donor network

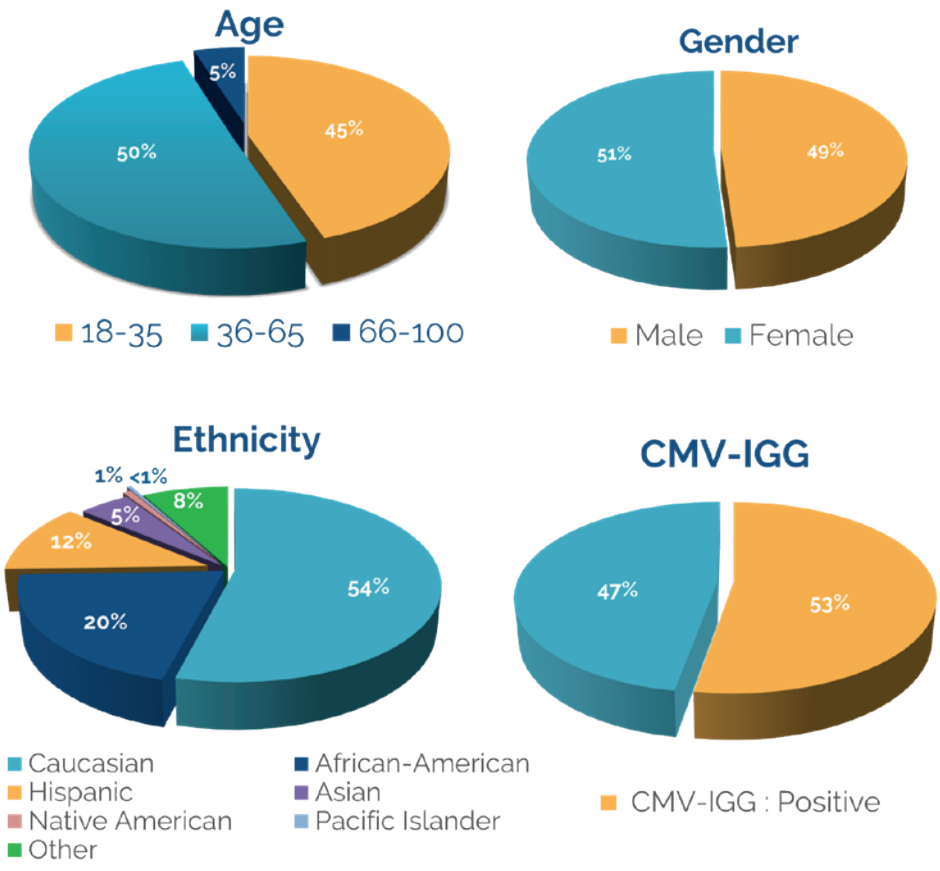
Access to a robust donor pool can be essential to the successful development of cell and gene therapies. With 4 locations nationwide, the CGT donor pool is one of the largest HLA-typed and most characterized in the industry. All collection centers are FDA registered, CLIA registered and streamlined under one Quality Management System (QMS) to support one project across multiple sites. We are committed to finding the right donors for a project and will consult with you to devise the best strategy to leverage our donor network. Choosing a capable healthy donor provider and partner for cell and gene therapy development starts with a reliable donor base and continues with further downstream capabilities. All CGT locations contain on-site state-of-the-art laboratories for providing end-to-end services such as cell processing and isolation. Clients have the option for products to be cryopreserved or shipped out fresh immediately after collection from a donor. We also offer customizable and location-specific donor or patient recruitment, testing, documentation and project management to facilitate a successful donor pool for your project.

Donor Recruitment Expertise and Services

Healthy donors provide the source material for many advanced cell and gene therapies currently in development. Program success often depends on finding the right donor source material from a provider that can appropriately support the evolving clinical phase of a project. CGT offers unique services to identify donors based on data in our characterized donor pool. Additionally, CGT handles donor logistics ranging from screening for target genetic markers to customized IRB-approved consent forms or specific donor infectious disease testing needs.

Our recruitment team utilizes grassroots and community-based methods to engage with new donors, and actively seeks the best donors for allogeneic collections through a variety of donoration drives and local events. A dedicated recruiter and customer service representative on our team is available to manage client or program-specific donor pools.

CGT Donor Pool Demographic Statistics



Collection Facilities

CGT technician operating Terumo Spectra Optia® Apheresis machine

Cellular starting material is essential for cell and gene therapies currently in development. CGT collects and provides this critical raw material using our network of privately owned and operated sites, phlebotomists and apheresis technicians with verified training under one Quality Management System (QMS). Our technicians ensure every clinical pre-screen and collection is performed in accordance with our documented and controlled procedures, and CGT Quality Assurance reviews each collection for compliance with GMP. CGT is audited by regulatory bodies and clients for quality and compliance.

All CGT donor and patient collections take place in clean, individual private suites for a safe and comfortable donation experience. Clinical Leukopaks are collected on the regulated and FDA approved closed system Terumo Spectra Optia® Apheresis machine. CGT employs an RN supervisor at each site, has two Medical Directors on staff and maintains the appropriate FDA registrations, CLIA registrations and State Licensure to collect and ship clinical material intended for further manufacture.

Strategic Locations for Manufacturing Partners

CGT Global has created a strategic network of cell collection centers with the cell and gene therapy industry in mind. Knowing that many therapeutic developers utilize third party manufacturing or CDMOs, we fulfill clinical collections intended for further manufacturing from all 4 collection facilities near major US-based CDMO partners. We can also work directly with your CDMO or manufacturing partner to simplify the fulfillment of our healthy donor products or patient collections. Utilizing our coast-to-coast footprint, CGT can mitigate supply risks caused by shipping delays, natural disasters, COVID closures, and other unforeseen circumstances. Due to CGT Global's crucual work during COVID we never closed our doors and supported our clients during the 2019 - 2021 global pandemic.

Proximity to Major CMOs

Boston, MA


Folsom, CA


East Norriton, PA

Customization and Process Flexibility

CGT offers a streamlined startup process and a flexible solution for GMP-compliant healthy donor starting material intended for further manufacturing. As you navigate through the startup and ordering process provided, CGT will collaborate with you directly to formulate a custom solution that will fit your specific needs all the way from donor recruitment to product fulfillment. Contact a representative to schedule an introductory or exploratory evaluation of your program.

Common process customizations:

- ✓ Location-specific donor collection in geographic proximity to your Manufacturing facility
- ✓ Complex donor screening and pre-qualification (see page 14-15)
- ✓ Specific donor recruitment or eligibility criteria
- ✓ Additional infectious disease testing (HHV-6, 7, 8, Babesia, Toxoplasma etc.)
- ✓ IRB-approved donor Informed Consent Forms (ICF)
- ✓ Supplemental Donor History Questionnaires (DHQ)
- ✓ Customized Certificate of Analysis (CoA)
- ✓ Analytical testing & other donor or collection characterization
- ✓ Patient specific support and collections
- ✓ Shipping containers and carriers

Clinical Onboarding to Ordering

Confidentiality agreement mutual execution

Meet with a sales representative

CGT clinical project request form completion

Contracts

- MSA / Supplier Agreement
- Quality Assurance Agreement
- Statement of Work

Quality Assurance audits / questionnaires

Quotation / PO submission

Customizable donor recruitment and screening

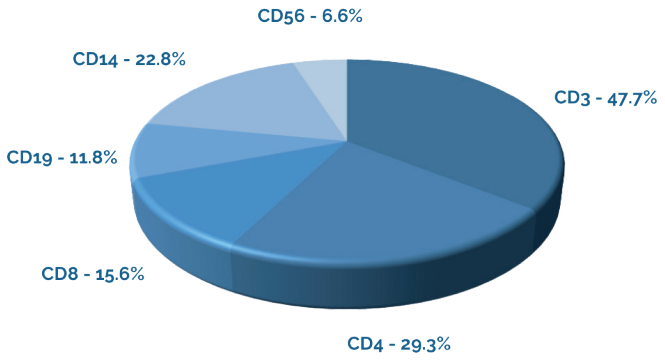
Can occur in parallel with above steps

Clinical GMP-compliant healthy donor collections

Clinical Products

Clinical Leukopaks

CGT Clinical Leukopaks are collected from IRB-approved consented donors or approved patients at 3 coast-to-coast FDA registered collection centers by qualified and trained staff using the Terumo Spectra Optia® cMNC collection protocol. Donor eligibility is determined following the AABB approved Donor History Questionnaire and in compliance with FDA 21 CFR subpart C infectious disease testing and medical history. CGT collection sites are FDA registered for HCT/P and our laboratories are CLIA registered. Standard infectious disease testing is performed by a qualified provider using FDA-licensed test methods. Collections are shipped fresh for same day, overnight or international delivery and documentation provided is customizable and compliant with GMP. CGT Quality Assurance reviews each batch for accuracy and release.



Normal Leukopak Cell Population Percentages

Average Leukopak TNC count

Avg TNC Counts	Volume (mL)	TNC (e9)
Average	185.17	15.07
Std Dev	18.37	0.77

- FDA 21 CFR 1271 compliant
- Collections occur under enhanced quality oversight with defined protocols
- FDA-registered collection centers
- Customizable donor selection process and infectious disease screening
- International regulatory compliance evaluation

Clinical Whole Blood

CGT collects Clinical Whole Blood at all collection sites by qualified and trained staff under an approved Batch Record using CPD anticoagulant bags. Donor eligibility is determined following the AABB approved Donor History Questionnaire and in compliance with FDA 21 CFR subpart C infectious disease testing and medical history. CGT collections are performed on-site at our CLIA registered and HCT/P FDA registered cell collection centers. A qualified provider performs standard infectious disease testing using FDA-licensed testing methods. Documentation can be customized to meet project needs and GMP compliance. CGT Quality Assurance reviews each batch for accuracy and release before product is shipped fresh for same day, overnight or international delivery.

Clinical Leukopak and Whole Blood Specifications

Clinical Donor Eligibility		Clinical Capabilities		
			Leukopak, Fresh	**Whole Blood, Fresh**
Donor Characteristics	Healthy donors, age 18-65 years old Backup donor included *Specific donor requirements available on request and subject to additional fee*	**GMP compliant Collection Centers**	Folsom, CA East Norriton, PA Boston, MA *FDA and CLIA registered* *Location specific donor recruitment available and subject to additional fees*	Folsom, CA East Norriton, PA Boston, MA FDA and CLIA registered Location specific donor recruitment available and subject to additional fees
Donor Consent	IRB-approved donor informed consent for further manufacture and commercialization *Modifications subject to fee*			
Donor History	Donor History Questionnaire compliant with AABB DHQ for Hematopoietic Progenitor Cells (HPC-DHQ)	**Catalogue Number**	CG-LE010F Includes Leukopak, standard donor screening and backup donor on-site *Additional products and services quoted separately*	CG-PBCPD250F Includes Whole Blood collection, standard donor screening and backup donor on-site *Additional products and services quoted separately*
Donor Physical Exam	Included			
Donor Eligibility Screening	Performed within 7 days of collection FDA Licensed testing compliant with 21 CFR Part 1271 for donor eligibility and performed by CLIA licensed laboratory Full Panel details: ◦*HIV I & II Ab + Reflex* ◦*HIV/HBV/HCV NAT* ◦*HCV Ab* ◦*HBV Ab Core + Reflex* ◦*HBV Ab Surface Ag + Reflex* ◦*HTLV I & II Ab + Reflex* ◦*Syphilis Ab* ◦*West Nile Virus NAT* ◦*T. Cruzi (Chagas) Ab* ◦*CMV Total* ◦*CMV Total with Reflex to IgM (Only performed if CMV total test result is positive)* ◦*CMV Total with Reflex to IgM and IgG/IgM (Only performed if CMV total test result is positive)* ◦*Zika NAT* inquire*	**Description**	Leukopak, Full collection, Fresh Clinical (GMP compliant)	Whole Blood, Fresh *Clinical (GMP compliant)*
		Anticoagulent	ACD-A	CPD available
		Cell Count/ Volume/ Viability	Target 10 Billion WBC *Actual donor collection yield may vary* ≥ 90% viability	250mL (CPD)
		Quality & Regulatory	QC and QA review and release of Summary of Record and Certificate of Analysis Performed under QMS controlled batch record and GMP compliant *Inquire for addtl regulatory support*	QC and QA review and release of Summary of Record and Certificate of Analysis Performed under QMS controlled batch record and GMP compliant *Inquire for addtl regulatory support*
		Shipping	Validated shipping containers available	Validated shipping containers available
Additional Infectious Disease Testing	*Available upon request and subject to additional fees*	**Price**	Custom *Inquire for full project questionnaire*	Custom *Inquire for full project questionnaire*
HLA Testing, KIR Typing & other characterization	*Available upon request and subject to additional fees*			

Clinical Donor Screening

Allogeneic cell and gene therapies such as CAR-T require the right donor and must often be selectively qualified and vetted prior to providing the raw material used in clinical manufacturing processes. This material is often subject to more extensive testing, and requires donors who are reliable and eligible for donation under 21 CFR 1271 subpart C if selected for clinical collection.

At CGT, we recognize this need in our industry and offer a unique product dedicated to finding the right donor on a program-specific basis and managed by our donor recruitment and collection staff accordingly.

This service includes: Leukapheresis, Whole Blood, Cryopreserved PBMCs

- ✓ FDA compliant Infectious Disease Testing panels
- ✓ Additional Infectious Disease Testing provided by approved vendors
- ✓ Donor characterization including HLA, KIR, genomic screening
- ✓ Location-based donor recruitment for supply chain optimization
- ✓ Dedicated donor management to your clinical program
- ✓ Further customization by evaluation

CGT donor undergoing screening

Clinical Donor Screening

PRODUCT CODE	DESCRIPTION	FORMAT	CONTENTS
CGSCRN-LE002.5F	1/4 Leukopak for Clinical Screening	Fresh	2.5B TNC
CGSCRN-LE005F	1/2 Leukopak for Clinical Screening	Fresh	5B TNC
CGSCRN-LE010F	Full Leukopak for Clinical Screening	Fresh	10B TNC
CGSCRN-PBMNC015C - 300C	PBMNC for Clinical Screening	Cryopreserved	15M - 300M PBMNC
CGSCRN-PBEDT010F - 100F	Whole Blood Vacutainer - EDTA for Clinical Screening	Fresh	10mL - 100mL

SERVICE CODE	DESCRIPTION
CGSCRN-HLAFULL	NGS: HLA Typing Class I & II For Clinical Screening
CGSCRN-NORPD0-3M	No Repeat Donors 0-3 Months For Clinical Screening
CGSCRN-DNRRECRUIT	Donor Recruitment For Clinical Screening
CGSCRN-DNRAGE18-35	Donor Age Request 18-35 For Clinical Screening
CGSCRN-DNRAGE36-65	Donor Age Request 36-65 For Clinical Screening
CGSCRN-DNRGENDER	Donor Gender Request For Clinical Screening
CGSCRN-MEDREQ	Medication Request For Clinical Screening
CGSCRN-NOMEDREQ	No Medication Request For Clinical Screening
CGSCRN-NONSMOKER	Non Smoker For Clinical Screening
CGSCRN-ALLERGYREQ	Allergy Request For Clinical Screening
CGSCRN-DNRBMICUS	BMI Custom For Clinical Screening
CGSCRN-HLASPEC	HLA Specific Request For Clinical Screening
CGSCRN-FLOWRPT	Raw Material Flow Report For Clinical Screening
CGSCRN-CMVPOS	CMV Positive For Clinical Screening
CGSCRN-CMVNEG	CMV Negative For Clinical Screening
CGSCRN-EBVNEG	EBV Negative For Clinical Screening
CGSCRN-EBVPOS	EBV Positive For Clinical Screening
CGSCRN-COVIDRTPCR	IDS: COVID-19 RT-PCR For Clinical Screening
CGSCRN-COVIDSER	IDS: COVID-19 Serology For Clinical Screening
CGSCRN-DNRABO	Blood Type For Clinical Screening
CGSCRN-DNRRH	RH Factor For Clinical Screening
CGSCRN-DNRABOMATCH	ABO Match For Clinical Screening
CGSCRN-CUSIDTEST	Custom Testing Panel For Clinical Screening
CGSCRN-IDSCGSTD	IDS Testing - FDA 21 CFR 1271 Panel For Clinical Screening
CGSCRN-IRBAMEND	IRB Amendment For Clinical Screening
CGSCRN-CUSFLOW	Flow Cytometry Custom For Clinical Screening

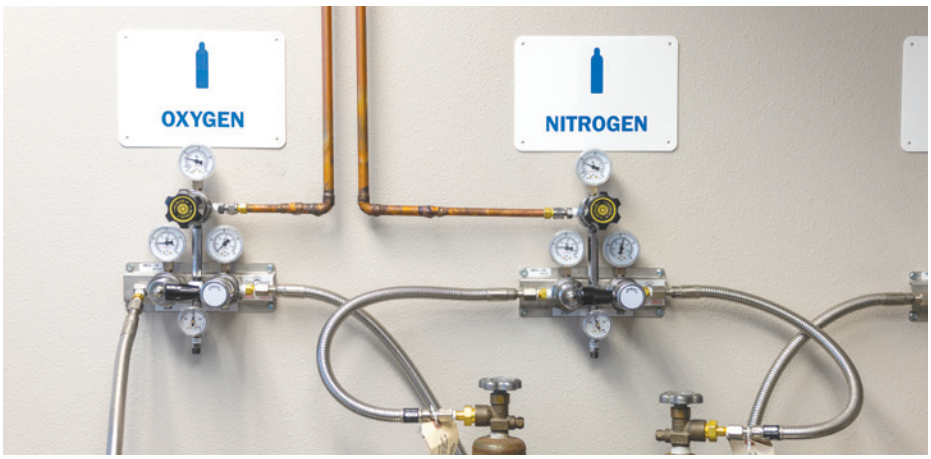
Donor reviewing Informed Consent Form at CGT Clinic

Clinical Laboratory Capabilities

Working in concert with researchers and hospitals to put patients first

CGT proudly operates two BioSpherix Xvivo® X2 closed system ISO5 GMP units within its laboratory, fully outfitted to deliver clinical grade GMP compliant starting material for cell and gene therapy projects. The environment in the 2 suite BioSpherix Xvivo® X2 is calibrated to ensure optimal conditions for cells to thrive, including airflow, gas, and temperature regulation. This expertly designed compact cleanroom isolator allows laboratory technicians to operate freely within the laboratory, while never compromising samples within the unit through human error and contamination. The Xvivo® provides continuous audit tracking - monitoring particle count, environment, user logs, outages and errors - meaning full accountability at every single step.

The CGT mission is to help bring treatments and cures to patients at an accelerated pace. Utilizing this compact, efficient, highly effective technology, we can help clients scale therapies without the extreme overhead cost. CGT makes it possible for you to bring life-changing therapies to the end user, the patient, as a first line of defense against disease.



CGT gas exchange system

Closed System Cell Manipulation

CGT is proud to house the CliniMACS Prodigy® on-site. This device distills a full scale GMP laboratory into a single unit capable of performing cell isolations and manufacturing clinical grade products for pharmaceutical, therapeutic devices, allogeneic and autologous production. The closed system produces GMP grade cell isolations straight from apheresis without any exposure to external environmental contaminants, ensuring patient sample integrity is never compromised.

Through this groundbreaking device, CGT can partner with clients to run samples and create a cell therapy product, alleviating the need for hospitals to house and operate cumbersome laboratory equipment. This closed system processing is approved by the FDA for clinical use and Miltenyi offers multiple isolation kits, or custom technology can be uploaded onto the device as needed for specific projects under research partner's or hospital's regulatory compliance.

CliniMACS Prodigy® close up

Our Team

CGT Laboratory Team

Headquartered in Reno, Nevada, CGT Global is a leading global provider of human primary cells, stem cells, bone marrow, cord blood, peripheral blood, and disease-state products. Our products are used for research and development, clinical trials, and commercial production of cell and gene therapies (allogeneic or autologous) by academic, biotech, diagnostic, pharmaceutical and contract research organizations (CRO's).

CGT Global is registered with the U.S. Food and Drug Administration (FDA) and has over a dozen global distribution partners and three (4) privately owned locations in the United States. It has been ranked by Inc. 500 as one of the fastest growing companies in the U.S. Learn more at www.cgt.global.

Learn more!

Our Mission is to Accelerate the Cure and Prevention of Significant Medical Conditions at Life-Changing Speed

We want to help you be successful in everything that you do. Our primary focus is how we impact patients, and we do that through helping you succeed at your projects. Our team is available to discuss the ways in which we can support you at any stage of your research.

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CONTACT US
Scan the QR code we want to hear from you.

Cate Spears, CEO and Founder of CGT Global

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