GLOBAL

The One-Stop-Shop, Full-Service CRO That Has Your Back

Specializing in Medical Devices, In Vitro Diagnostics, Complex Biologics, Drugs, & Combination Products

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Meet GLOBAL

The Full-Service CRO That Has Your Back

We provide healthcare innovators unparalleled research and clinical development support, regulatory consulting, and writing services through customized collaboration, problem solving, and technical expertise.

Why Choose GLOBAL?

- Proven track record supporting clients across multiple sectors
- Repeat business is the norm, not the exception
- True partnership for companies and projects of all sizes

Our Story

Our founder, Emily Stephens, worked in the medical device and biologics industries for thirteen years before launching GLOBAL in early 2014.

After years of 60-hour work weeks for CROs that were notorious for burning out workers, she developed an autoimmune disease that would forever change her vision of the medical writing industry. Life was too short for burnout. She wondered,

> What would happen if there was a company that treated workers with respect, loyalty, and deeply advocated for their work/life balance?

Out of this question GLOBAL was born and the outcome has been spectacular: We attract the best, who then perform at their best, because this is a place where we fiercely take care of each other.

I guess you can say we do things differently here at GLOBAL.

We're the first medical writing company to offer unlimited PTO, flexible schedules, company-paid, best-in-class medical benefits, quarterly bonuses, and a generous profit-sharing plan to our employees. We approach projects in teams to allow us more flexibility and a balanced support system for our clients.

Emily Stephens, Founder & CEO

Ways of Working

Billing

We only bill for hours worked. Proposals represent a good faith estimate of hours relative to the scope of work (SOW). We can set up SOW arrangements that meets your needs: dedicated FTEs, hourly FTEs, T&M, milestones, project-by-project.

Location & Connectivity

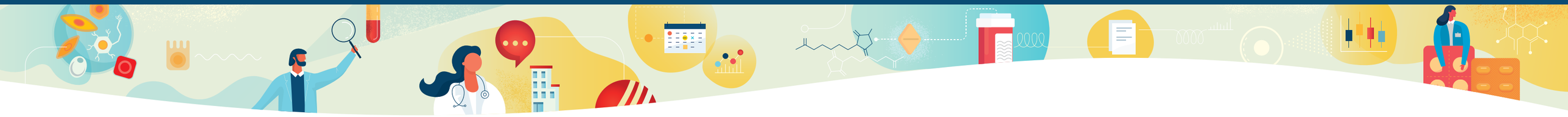
The team is 100% remote, working out of home offices. Travel to client sites can be arranged on an as-needed basis. Meetings are conducted using Microsoft Teams. Sharepoint or VPN access can be used for secure file-sharing or client computers can be issued to select team members.

Experience & Flexibility

We offer a wealth of large pharma and biotech experience while maintaining the flexibility of a small company. Let us build a team that fits your unique needs.

Matrixed Team

Each project has a lead single point of contact. Supporting the lead are subject matter experts chosen according to your project needs. The matrixed team model offers a great value proposition to clients for the best service.



Clinical Research

ALL TRIAL TYPES AND PHASES
- Phase I – IV Support for Pharma Trials
- Feasibility, Pivotal, and Post Market Support for IVD and Medical Devices

PROJECT MANAGEMENT
- Project Leadership
- Site Management
- Clinical Strategy Development
- Budget and Resource Allocation
- Study Logistics
- Vendor Selection and Management

DOCUMENTS
- Protocols and Amendments
- Instructions for Use
- Investigator Brochures
- Informed Consent Forms
- Financial Disclosure Forms
- Clinical Trial Investigator Agreements
- CEC and DSMB Charters
- Statistical Analysis Plans
- Randomization Schedules

TRIAL EXECUTION
- Country and Local Regulatory Submissions
- Site Selection, Qualification, and Initiation
- Investigator Meeting Planning and Execution
- Site Training
- Case Support
- Trial Master File
- Patient Recruitment

DATA MANAGEMENT
- EDC/Paper Data Capture Solutions
- Data Management Plan
- Case Report Forms
- Data Entry/Processing
- Data Review and Query Resolutions
- Data Archiving

MONITORING
- Site Qualification Visits
- Site Initiation Visits
- Interim Monitoring Visits
- Close-Out Visits

SAFETY OVERSIGHT
- CEC/DSMB/Steering Committee Creation and Oversight
- Adverse Event Reporting
- Adverse Event Adjudication
- Medical Monitoring
- Adverse Event Coding

RESEARCH COMPLIANCE & EDUCATION
- Clinical SOP Development
- Mock Audits
- Audit Support
- GCP Training

Our Approach Provides Sponsors with Maximum Flexibility

Full-Service Model
Hand off your clinical development projects and rest assured that GLOBAL will execute your vision, integrate industry best practices, and uphold all regulatory requirements.

OR

Partnership Model
GLOBAL can walk you through the planning, execution, study closure, and reporting process, while identifying specific tasks that can be done in-house to provide greater savings.

Commitment & Transparency
GLOBAL is committed to your long-term success. We believe study success is based on building quality into the process from the beginning.

GLOBAL

How We Work

We work with your team and subject matter experts to develop a data-driven messaging strategy for your program across all documents. This strategy ensures that document users, whether clinical decision makers or regulatory approvers, have quick access to the product information that is most relevant to their needs.

100% repeat business awarded for CSRs and protocols

What we do

- **Content authoring**
- **Technical editing and formatting**
- **QC review**
- **Document publishing**
- **Project management**

Clinical Documents

Protocols

- Synopses
- Full protocols
- Amendments (global and region-specific)

Investigator Brochures

- Full IBs
- IB updates

Clinical Study Reports

- Full
- Abbreviated
- Interim
- Synoptic

Informed Consent Forms & Patient Information Leaflets

Patient Safety Narratives

Regulatory Documents

Investigational Applications

- Investigator New Drug Applications & Clinical Trial Applications
- Applicable Common Technical Document summary modules, including the following:
  - General Investigational Plan
  - Nonclinical overview (Module 2.4)
  - Nonclinical written summaries (Modules 2.6.1, 2.6.2, 2.6.4, & 2.6.6)
  - Nonclinical tabulated summaries (Modules 2.6.3, 2.6.5, & 2.6.7)
  - Nonclinical study reports (Module 4.2)

Briefing Books and Meeting Request Letters

Pediatric Investigation Plans & Pediatric Study Plans

Risk Management Plans

Marketing Applications

- New Drug Applications, Biologics License Applications, & Abbreviated New Drug Applications
- Applicable CTD summary modules, including the following:
  - Clinical Overview (Module 2.5)
  - Clinical summaries (Modules 2.7.1 through 2.7.6, including Integrated Summary of Safety & Integrated Summary of Efficacy modules)
  - Tabular listing of all clinical summaries (Module 5.2)
  - Clinical study reports (Module 5.3)

Other Health Authority Communications

- Orphan Drug Designation requests
- Breakthrough Therapy Designation request

Safety Management and Pharmacovigilance Documents

(aka, Aggregate Safety Reporting)

- 120-Day Safety Update Reports
- Development Safety Update Reports
- Periodic Safety Update Reports
- Periodic Benefit-Risk Evaluation Reports
- Patient Safety Narratives

LEARN MORE | **myglobalcro.com/clinical-writing**

Writing and Consulting for MDR Implementation

One of the qualities that sets GLOBAL apart is the flexible approach we take to resourcing your projects. By leveraging our consultants, project managers, and subject matter experts, we will build a blended team to achieve your project goals.

Our EU MDR consultants can help determine the appropriate regulatory and clinical activities to achieve EU MDR compliance. After creating a compliance plan, our Clinical Research team can plan and execute the clinical activities, and our medical writers can develop your clinical evaluation and other submission materials.

35+ US-based writers and consultants

100+ CERs written each year

15+ Manufacturers supported

EU MDR Consulting

- Guidance regarding new product development and regulatory strategy
- Execute clinical/regulatory gap assessments
- Develop standard operating procedures and associated templates
- Establish pre- and post-market strategies for clinical evidence
- Provide Notified Body response strategy and support
- Plan Technical Documentation remediation

Clinical Evaluations

- Manage and write CEPs and CERs
- Create an evidence strategy and establish safety and performance outcomes and their acceptance thresholds
- Execute systematic literature reviews, including the literature search, analysis, and summary
- Develop robust equivalence arguments
- Analyze product risk-benefit

PMCF/PMS

- Determine and develop the appropriate PMCF strategy and activities
- Complete PMCF Plans, PMCF Evaluation Reports, PMS Plans, PSURs, and PMS Reports
- Execute PMCF activities including literature reviews, robust surveys, chart reviews, or clinical studies

Patient and HCP Facing Documents

- Execute SSCP
- Update IFUs to MDR
- Prepare PILs

Project Management

- Create, optimize, and maintain schedules for EU MDR deliverables
- Build and implement standard project timelines, establish processes, and map dependencies among workstreams
- Determine resource projections for short-, medium-, and long-term schedules
- Implement tracking and projection tools to increase team efficiency

Training

- Provide comprehensive team training on EU MDR Requirements
- Deliver in-depth training on executing documentation related to Clinical Evaluations/SSCP, PMCF, and PMS
- Option of an embedded writing resource to guide teams through the preparation of EU MDR deliverables

Other Services

Clinical Research

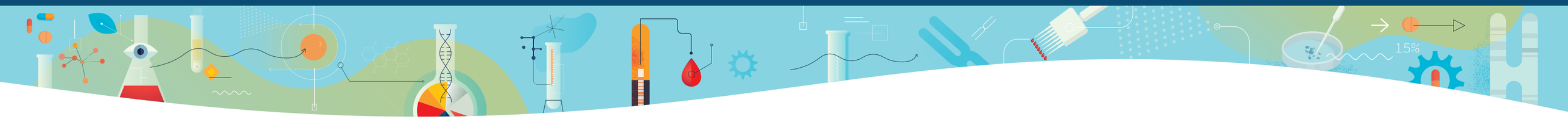
Our team creates a customized and flexible approach for your clinical trial needs.

→ See page 05 for additional information

Regulatory Technology

GLOBAL Exponential Technologies – Regulatory (GxT-R) Solutions builds software that improves regulatory intelligence and refines regulatory workflows.

→ See page 15 for additional information



IVD Services to Meet Your Regulatory Needs

REGULATORY STRATEGY EUROPEAN UNION

- Regulation (EU) 2017/746
- Notified body responses
- Postmarket planning, including PMPF
- IVDR Standard Operating Procedure
- IVDR Work Instruction
- IVDR document templates

MEDICAL WRITING PERFORMANCE EVALUATION

- Performance Evaluation Plan
- Performance Evaluation Report
- Postmarket Surveillance Plan
- Postmarket Surveillance Report
- Postmarket Performance Follow-up Plan
- Postmarket Performance Follow-up Report
- Periodic Safety Update Report
- Summary of Safety and Performance

CONFORMANCE ASSESSMENTS

- General Safety and Performance Requirements
- ISO-13485 (Quality Management Systems)
- ISO-14971 (Risk Management)
- IEC-61010 (Electrical Equipment)
- IEC-62304 (Software)

REGULATORY STRATEGY UNITED STATES FDA

- Premarket Approval
- 510K
- Special 510K
- Emergency Use Authorization

PROJECT MANAGEMENT

- Project leadership
- Timeline management
- Priority management
- Stakeholder coordination

BOOTCAMP SERVICES

- Regulation (EU) 2017/746
- Performance Evaluation of IVDs

Our IVD Team is experienced in providing CE-marking support for unique IVD devices, including:

- Companion Diagnostics
- Point-of-Care Devices
- Devices that are Software
- Accessory Devices

Regardless of whether the device is considered a legacy device or a new product, we have the experience and expertise to support your submissions.

CHEMISTRY, MANUFACTURING, & CONTROLS

Regulatory and Technical Consulting

Our world-class scientists and regulatory experts can guide your product from inception to bedside and through the many technical and regulatory development hurdles along the way. We apply our knowledge of health authority requirements, technical acumen, and industry best practices to prepare technical and regulatory documents that are fit for purpose, scientifically sound, and aligned with agency requirements. Please see our most common services below and reach out to explore how we can best support your team!

Technical Services

- GxP documentation (for example, batch records, SOPs, protocols, reports)
- Deviation investigations
- Compliance gap assessment
- Strategic review of development plans
- Pre-approval inspections and readiness
- Comparability studies
- Commercial control strategies
- Risk assessments
- PPQ and CPV master plans, protocols, and reports

Regulatory Services

- Investigational new drug and clinical trial applications
- License applications
- DSURs, annual reports
- DMFs
- Post-approval supplements
- DEA Quota requests
- Agency meeting requests, briefing books, and interactions
- Responses to agency information requests, clinical holds, and complete response letters
- Change control assessments
- RLD and IIG excipient reviews
- Due diligence and gap analyses
- Controlled correspondence
- Regulatory advocacy and policy

REGULATORY OPERATIONS - PUBLISHING & SUBMISSION MANAGEMENT

eCTD Publishing & Submission Management

We are prepared to submit your eCTD-compliant submissions!

Global's dedicated eCTD publishing team has decades of combined industry experience in Submission Project Management and Submission Publishing execution.

Our team will bring to your project:

- Industry best practices
- Submission compliance at every step of the process
- In-depth technical knowledge of all eCTD guidance and requirements
- A keen awareness and understanding of the entire submission landscape
- Help establishing the best lifecycle management strategy for the life of your product

Customization

- Flexibility to maintain your preferred document style and templates, or
- Convert your content into our industry-standard, best practice style templates

We work with exceptional submissions management software to efficiently publish, validate, and review your eCTD submissions to support your team's race to meet deadlines.
Contact us for more information or to set up a quick initial assessment.

GLOBAL Exponential Technologies - Regulatory (GxT-R) Solutions

GxT-R provides software-based tools and services to improve regulatory submission efficiency and quality through automation and advanced intelligent architecture.

- Streamline and automate your regulatory submission preparation & post-submission follow-up
- Leverage proprietary IT solutions to automate data extraction & validation, literature screening, complaint classification, and content authoring
- Advanced, intelligent software tailored to fit your regulatory processes and workflow
- Improve efficiency & quality of work for regulatory affairs, clinical research, and quality management professionals

Regulatory Submission Management

ADDM™ Advanced Deficiency/Document Data Management

Meet the ADDM™ suite of customizable tools, designed to manage your IVDR, EU MDR, and FDA submissions; EU MDR remediations; MDD updates, eCTD submissions and more.

ADDM™ Track

Regulatory Project Management Tool

- Track submissions through approval
- Manage submission tasks and documents
- Easy set-up with pre-determined templates
- Monitor Notified Body assessment reports
- Coordinate team and business unit responses
- Improve & enhance regulatory data management

ADDM™ Trend

Regulatory Feedback & Response Analysis

- Consolidate & analyze regulatory feedback
- External & internal audit management
- Identify submission strengths & weaknesses
- Improve future submission focus, regulatory compliance, and submission efficiency
- Automated regulatory feedback data upload

Regulatory Automation

RegWriter

Automated Authoring
(Coming 2023)

- AI-assisted regulatory document composition and content authoring
- Intelligent software that pulls data from multiple source documents for writer review & summary
- Adaptable to any regulatory standard & submission type such as CERs, PERs, BLAs, & SSCPs
- Works with manufacturer's templates to return data that is document ready
- Shorten & improve regulatory document prep time

ALiSE 2.0

Accelerated Literature Screening & Extraction Module *(Coming 2023)*

- Proprietary Artificial Intelligence (AI) pipeline for scientific & clinical literature
- Automatically extract clinical data from published and unpublished literature
- Customizable AI-assisted literature screening
- Extract & compile scientific data from published/unpublished literature, clinical study reports, and other forms of written scientific data
- Compile data into summaries & tables

Smart Complaints

Complaint Category Classification Tool
(Coming 2023)

- Categorize & summarize safety data and complaints
- Safety trend regulatory standard summaries
- Complaint, malfunction, and AE/SAE classifications

Additional Products and Services

(Available Now)

- Software design, development, and evaluation
- QMS/eQMS development and deployment
- Regulatory strategy, compliance, validation, and qualification

Partnership and Transparency Approach

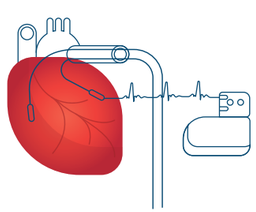
Are you interested in maximizing your ability to automate and improve your global regulatory processes? GxT-R would love to partner with you. Our experts are ready to:

- Ensure your IT systems, SOP's, and processes comply with all applicable guidelines and standards
- Identify specific tasks and larger projects to leverage automated intelligent solutions
- Build and deploy automation solutions within your cloud infrastructure or build and host within our own secure cloud environment.
- Create fully functional and productive data analytics
- Provide secure, custom, web-based databases

In-Person and Virtual Trainings

GLOBAL offers a variety of intensive, hands-on, in-person and virtual training programs that can be adapted to your organization's specific needs. Whether your team needs a foundational understanding of how to author a specific document, guidance on industry best practices, or clarity on how to navigate regulatory requirements, we will customize a training program tailored to your specific goals.

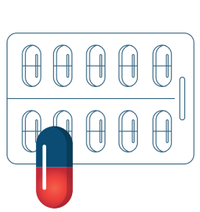
Some of our most requested training topics include:



Medical Device Regulation (MDR) (EU) 2017/745

In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746

Clinical Evaluation Report (CER) Writing



The Drug Development Pathway

Need a customized training program on a topic not listed here?
Email **info@globalrwc.com** and tell us more. We will pair best practices in educational principals with our hard-earned industry knowledge to develop a training program just for you!

Regulatory Writing Internship

The GLOBAL Regulatory Writing Internship is an intensive training program designed for entry-level writers interested in a regulatory writing career at GLOBAL. The program focuses primarily on learning how to write and develop CERs and related documents.

What positions are available?

- Paid, full-time, remote position where learning is your job for the first months.
- As your skills progress, you'll transition to working under the mentorship of an experienced writer for experience on clinical evaluation strategies, project management, and regulatory knowledge.
- Interns who demonstrate mastery of key skills will be considered for promotion to a full-time salaried writing position at GLOBAL.

What's in it for you?

- Training, mentorship, and opportunities for advancement in an in-demand, highly skilled field
- Competitive starting pay and long-term opportunities for career growth
- Benefits including medical insurance and accrued PTO

What are the requirements?

- Ability to meet a full-time commitment (40 hours/week; standard business hours)
- Minimum master's degree in a related field
- US resident
- Interest in a career in regulatory/medical writing at GLOBAL

If you want a career that involves learning constantly, taking on new challenges, and helping people, then this might be just the field for you!
Email **internship@globalrwc.com** for more details.

Interested in how GLOBAL brings our Core Values to life? Here's what our employees have to say.

INTEGRITY

"I think that integrity is critical to all that we do. It is how we maintain our reputation both as an individual professional and also as a company. Ultimately it is our client's decision as to their proposed path forward. But our recommendations and our work product has to be focused 100% with that integrity intact, focusing on the regulatory requirements, honesty and transparency with data, and patient safety at first and foremost. We deliver that in what we do and we how we hold ourselves accountable to that."

COLLECTIVE INTELLIGENCE

"To me, our collective intelligence is part of GLOBAL's capital. It's the knowledge that we share with one another to problem solve and generate the highest quality of work for our clients. Example: my manager has a very strong technical ops background and his feedback on several client authored CTD sections was invaluable. He found and presented several potential compliance gaps which may have prevented possible observations during the Client's upcoming PAI."

AGILITY

"I never feel alone anytime that we're in a pinch I know that my colleagues are capable of reprioritizing whichever is most important for them. The same goes for me, the work is always reciprocated. That is one of the things that makes GLOBAL so special, is that we do approach it as a team, no one is left hanging out to dry, and that's a big reason we have been as successful as we have been."

INCLUSIVENESS

"'Inclusive' is welcoming to all different kinds of people and religions and sexuality, color, race, creed, the whole nine yards. In order for us to successfully be inclusive, each and every person on our team has to believe in and fight for it, or it's not going to happen."

SANCTUARY

"I feel that GLOBAL makes great effort to care for the well-being of their employees, from work-life balance focus and flexible PTO policies, to extremely generous medical benefits and 401k plans. We even have a paid workout hour each week (or a class we can participate in), and fun retreats (not stuffy meetings all day). GLOBAL embodies sanctuary, and is always striving to do better."

CURIOSITY

"Curiosity within GLOBAL partners so well with Collective Intelligence. The 'can do' attitude and innate curiosity to improve on our services to clients or widen our footprint is what makes GLOBAL so great! -- GLOBAL leaders I have worked with have enthusiastically supported and motivated team members to grow and promote curiosity."

CLIENT TESTIMONIALS

"Our company has benefited from GLOBAL's services since the end of 2017 and the provision of these services has been instrumental to the success of our company.
Based on our experience, what sets GLOBAL apart are the following attributes:

1) Depth of technical expertise

2) Work flexibility and responsiveness

3) Creative contracting solutions

In summary, I wholeheartedly recommend their services."

"Really wanted to give a shout out to all of you – I know some of this is completely thankless work, so I wanted you all to know how much I appreciate the efforts. The documents are really in fantastic shape. We're making headway closing/locking up at a fast clip, and it really is thanks to your organization, diligence, and utter setup of [COMPANY] for success in our final days leading up to publishing. So – thank you…!"

"You are one of the best in the business! Your sharpness in terms of connecting all critical parts of the large document and organization are just amazing and make you stand out. In addition, you did it with such ease. A major lift of burden from our shoulder!"

"The team at GLOBAL is a pleasure to work with, and the quality of their work is of the highest caliber.

GLOBAL truly understood the requirements of our project and the context within which we operate. They assembled a team with exactly the expertise we needed, and provided critical contributions from the very first conversation.
I was also impressed at GLOBAL's ability to contribute at both the tactical and strategic level. In previous experience, I found firms that provided one or the other, but not both. It was extremely valuable for our project to work with a group that could assist with the details while also keeping view of the overall strategy, and shift back and forth as the submission evolved."

"Awesome decision making along the way, super collaborative. Well done."

"I am blown away at the work product you provided. This is some of the best RA work I have seen in a very long time!!!!!!
I am speechless."

"I have known Em and the team at GLOBAL for several years and the projects that they have supported keeps surpassing my expectations. From day 1, whether it was a single CER or a package of projects, the team at GLOBAL showed up prepared, knowledgeable and dedicated to providing the highest quality within the time frame needed. When we experienced competing priorities within the program or where we weren't certain how to incorporate MDD/MDR lessons learned, GLOBAL proactively brought solutions to the table. Each individual there that I have worked with over the years has approached their project(s) with a true sense of partnership and desire to do what was in the best interest of my team/company.

As for Em, I can't say enough good things about her. Not only does she do a fantastic job steering the company, she does what is right for her employees and she is constantly thinking about how to improve the world around her. Every conversation that I've had with her has been a joy; she's energetic and embodies a positive can-do attitude."

"We really couldn't have done it without you, and certainly not within our extremely aggressive timelines!"

"Thank you and admiration for the incredible team you've assembled – this success is as much your success as it is our success!"

"I wanted to offer my sincere and heartfelt thank you for your excellence."

Looking for more details on what it's like to work with us? Email **info@globalrwc.com** and we'll send you a few glowing letters of recommendation from our clients.

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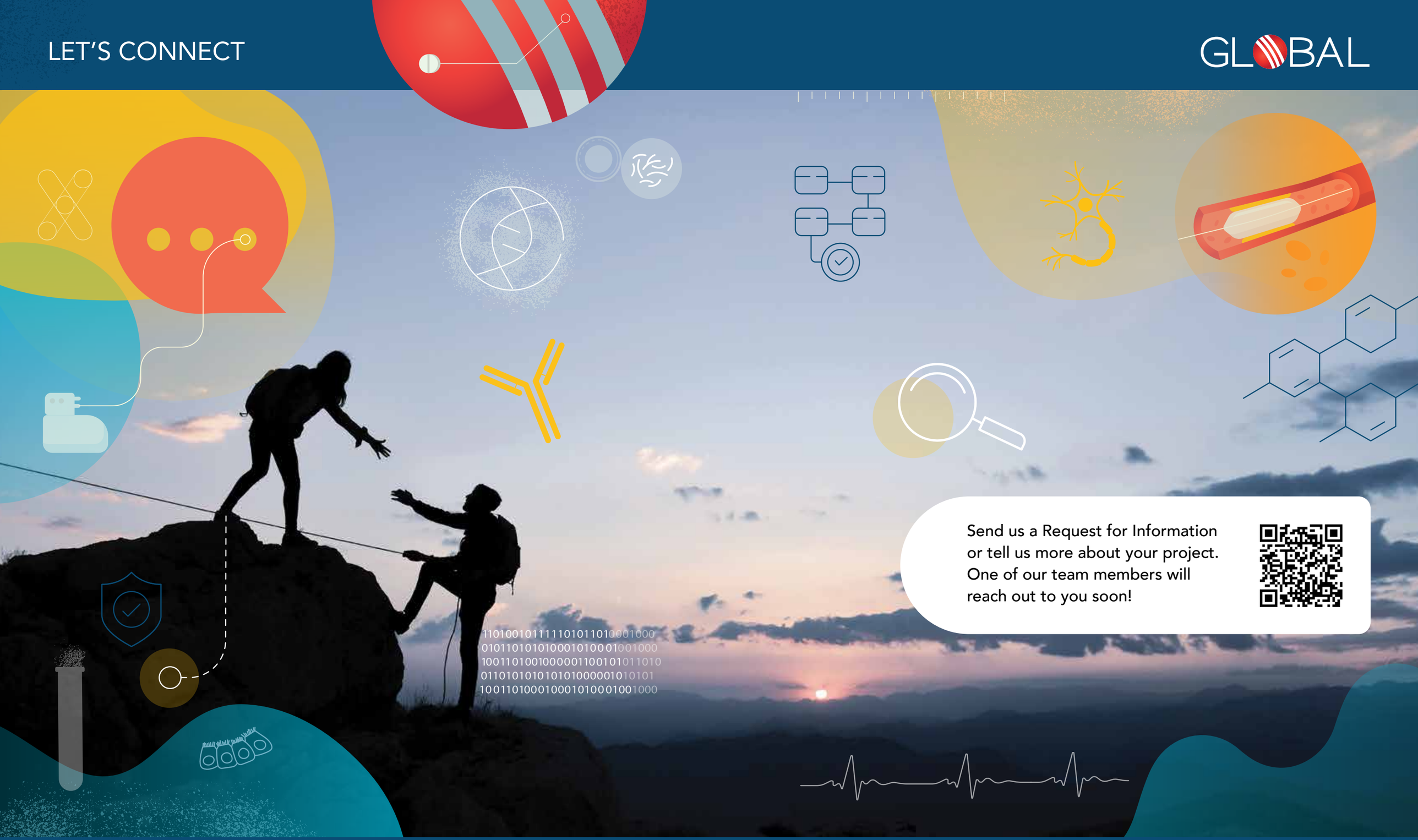
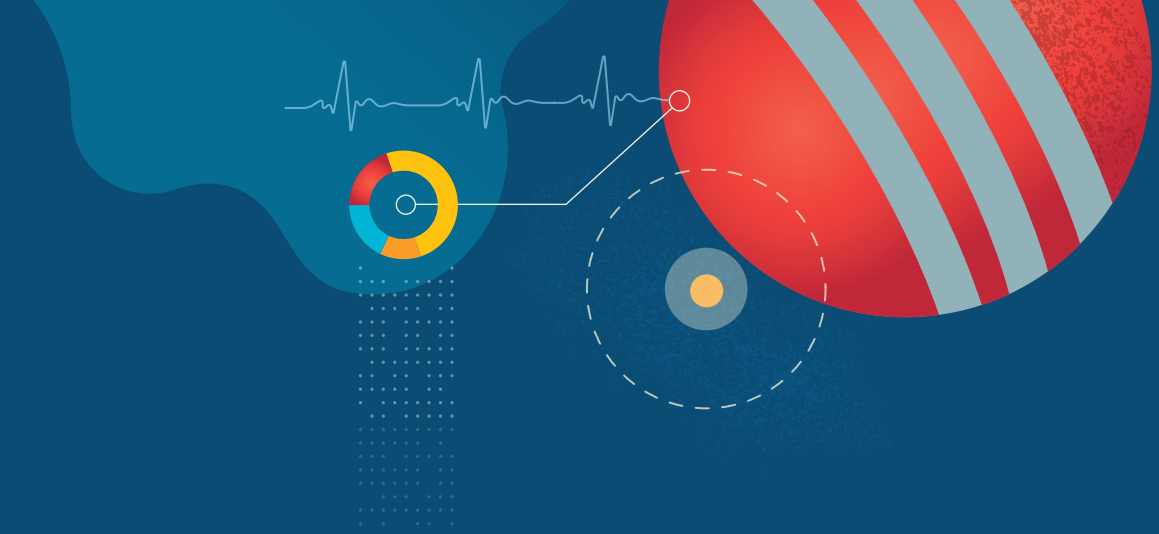


Send us a Request for Information or tell us more about your project. One of our team members will reach out to you soon!



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