



# WCG ThreeWire Site Support Services





## Who is WCG ThreeWire?

WIRB-Copernicus Group® (WCG™) is the world's leading provider of solutions that measurably improve the quality and efficiency of clinical research. As part of the WCG family of companies, WCG ThreeWire specializes in accelerating enrollment for global pharmaceutical and medical device trials by providing site-tailored patient enrollment support.



# Accelerate and Increase Enrollments While Reducing Your Site's Workload

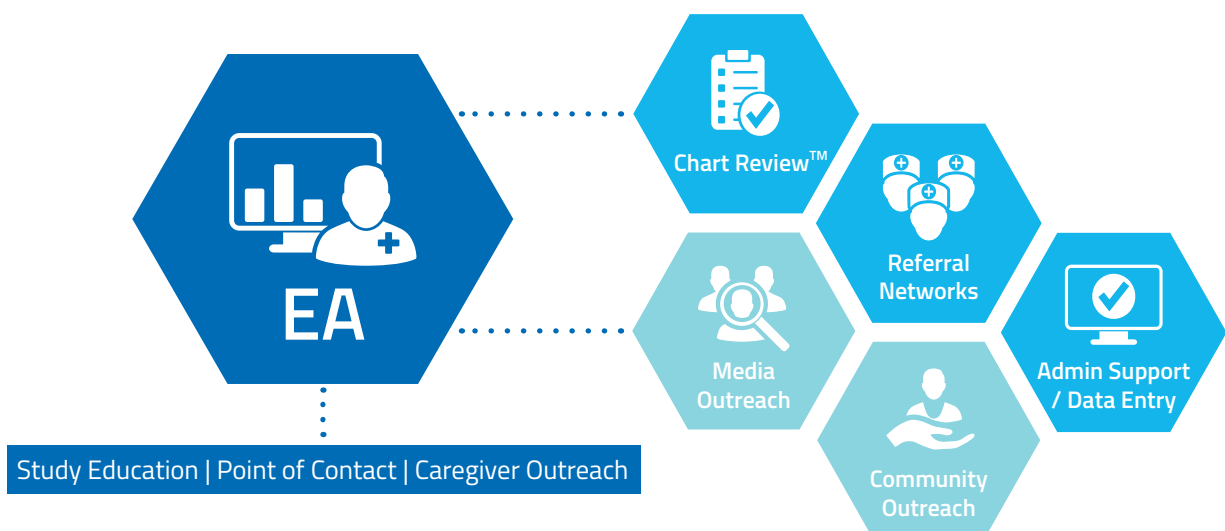
There is no one-size-fits-all approach to site enrollment. Accordingly, WCG ThreeWire develops a customized enrollment support strategy based on the study protocol and the patient profile. We then work with your site to specifically tailor that strategy to best suit your site, taking into account factors such as the size of your patient database, your site's staffing structure, patient indication, and protocol specifics. We will work with your team to deploy that recruitment strategy through our core service offering: **Enrollment Assistant™** Site Support ("EA"). EAs serve as a dedicated recruitment resource for a specific study being conducted at your site with a focus on recruitment related activities, allowing your team more time for patient care.

Placement of an EA is designed to support your study team and not cause additional work. Each EA is a healthcare professional who is identified and trained by WCG ThreeWire before assignment to your site. This training includes the study protocol, GCP, and the recruitment plan. After EA deployment, WCG ThreeWire will continue management of the EA, and provide oversight regarding execution of the recruitment plan ensuring it will not be an additional factor for your team to manage. The EA will become an extension of your study team subject to the investigator's direction.

## SITE SUCCESS THROUGH COLLABORATION & COMMUNICATION

Collaboration between ThreeWire, CRAs, Sponsors, and sites is essential in meeting the common goal of a smooth and efficient study. The following steps can be taken to optimize these goals:

- Share contact information and maintain open lines of communication
- Provide access to data reports and screening logs on a consistent basis in order to protectively monitor site progress
- Escalate site needs and concerns as they arise to ensure proper support is provided



# WCG ThreeWire Offers a Full Suite of Services to Accelerate Enrollment

Enrollment Assistants are highly qualified healthcare and clinical research professionals who execute site-customized recruitment and enrollment strategies. Working directly with your staff, our Site Specialist Team will establish the best tactics to accelerate study enrollment at your site. These tactics might include:

## WCG ThreeWire Chart Review™:

Comprehensive, methodical, and systemic process built on reimbursement/billing codes, ICD-10, and inclusion/exclusion criteria

- Retrospective Chart Review- Thorough review of your site's existing patient charts
- Prospective Chart Review- Ongoing review of upcoming scheduled visits or new charts of patients visiting your site

Enrollment Assistants can provide prescreening and scheduling for those individuals that have been identified using my-patient.com® which tracks and reports on each patient's progress throughout the recruitment process

## Referral Physician Networks:

Increases your site's enrollment through strategic physician referral relationships

- Interdepartmental Referral Networks: Identification all patient touch points in the patient's natural care pathway within your site's larger organization so as to introduce the study to care providers and potential patients
- External Referral Networks: Establishing referral pathways between your site, physicians, and clinics within your site's local community to build and then maintain referral relationships

## Community Outreach:

- Promotion of study awareness in and around your site to generate interest in the study, including:
  - Presentations and meeting with local advocacy groups
  - Attendance at local health expos, awareness walk/runs, and other events
  - Participation in site-sponsored indication related education events
- Community Health Talks®: Informational sessions designed to bring potential patients into a study discussion forum, including:
  - Engaging in one-on-one discussions with site staff
  - Pre-screening of potential patients and educating caregivers
  - Planning and logistics management for events to be held at or near your site

## Enrollment Assistant Media Referral Processing:

- Relieves your site of the burden of responding to all media referrals
- Provide same day (24 hour) response to all media referrals
- Appointment Scheduling and Follow-up
- Ensures only thoroughly pre-screened media referrals are scheduled First Office Visits
- Off hour ability to respond to media referrals including nights and weekends or other times when your site might be closed

### Data Entry and Query Resolution:

- Conduct data entry to address any backlogs at your site; assist in timely data lock and provide ongoing data entry maintenance as required freeing up time for your study team
- Facilitate and assist with query resolution including locating source documents and other missing information

### General Administrative Support, Including But Not Limited, to:

- Appointment Scheduling and Follow-up
- Patient Retention tactics such as ePRO/study diary reminders, thank you notes, reminder calls
- Medical Record Retrieval
- Monitor Visit Preparation
- Maintain Study Binder
- Transportation Assistance

### IT'S ALL ABOUT TEAMWORK!

The Enrollment Assistant™ is a partnership for success between your site, the Sponsor, and ThreeWire.

Our Site Services and Program Management teams are dedicated to working with you and your site to ensure all needs and accommodations are met.

Let's work together to ensure we meet our enrollment goals!

## TESTIMONIALS



"WCG ThreeWire's employees are professional and highly educated about the inclusion/exclusion criteria and helped to identify several patients that were subsequently enrolled in the study. This is a helping hand provided at no additional charge to sites, I know everyone could use additional help every now and again. ThreeWire is very easy to work with and I would highly recommend their services. If you're not using them you're missing out on potential subjects that may slip by!"

– CLINICAL RESEARCH COORDINATOR

"The WCG ThreeWire Enrollment Assistant™ was quick, accurate, and thorough."

– PRINCIPAL INVESTIGATOR

"We conducted a site monitoring visit last week and recognized that [EA Name Redacted] has done a great job with preparing the site for this visit. She made sure all data entry was completed in a timely manner and subject binders were in order. She is efficient with her time and manages the workload well. The site is happy to have her onboard and appreciates her work." – CRA



# WCG ThreeWire Offers a Unique Site Support Service

WCG-ThreeWire's Site Services team specializes in the onboarding of Enrollment Assistant support at all types of sites.



## ENROLLMENT ASSISTANT PLACEMENT OPTIONS

### 1. WCG ThreeWire Sourced Enrollment Assistants

WCG ThreeWire will provide a highly-qualified professional to work at your site as dedicated resource to complete important study-specific recruitment tasks. The EA will work as a member of your site's study team, and the EA's role will be documented on the Delegation of Authority Log. WCG ThreeWire will ensure any such person is trained on your site requirements applicable to the EA's duties.

### 2. Site Sourced Enrollment Assistants

WCG ThreeWire can utilize an existing site employee, provided they are suitably qualified, who is not currently on the study

team, to serve as the EA. This site employee will supplement his/her typical workweek with hours dedicated specifically to the recruitment of the WCG ThreeWire supported study. WCG ThreeWire will provide any such person with the same study-level required training and recruitment strategy guidance.

### 3. Remote Enrollment Assistants

WCG ThreeWire's team of Remote EAs can perform certain recruitment tasks from WCG ThreeWire headquarters in Eden Prairie, MN. This solution is great for sites that do not have workspace for an on-site EA or when work is best completed outside of typical business hours (nights and weekends). The WCG ThreeWire Remote EAs work in all major EMR systems and are able to work directly with your site's scheduling process and systems.

## ENROLLMENT ASSISTANT QUALIFICATIONS AND TRAINING

In addition to the core requirements, WCG ThreeWire EAs are selected based on the specifics of the protocol they are supporting, the patient population being recruited, and the tactics required to execute your site-tailored recruitment strategy.

Regardless of which EA placement option is used to place an EA at

your site, WCG ThreeWire's Site Services team will ensure that your EA is fully trained on the study protocol, WCG-ThreeWire recruitment processes, and when appropriate, your site-specific SOPs.

## YOUR WCG-THREEWIRE SITE SERVICES SUPPORT TEAM

A Site Onboarding Specialist will be assigned to your site to ensure efficient onboarding for your EA. We understand that each site has its own policies and procedures regarding onboarding and system access. Accordingly, your Site Onboarding Specialist will work with you to onboard your EA within your site's requirements. Once placed, an EA Manager will serve as your point of contact through the duration of EA support at your site. The EA Manager will be responsible for managing the EA's productivity as it relates to the patient recruitment efforts at your site.

## MY-PATIENT.COM®

Central to WCG ThreeWire's support is my-patient.com, our proprietary patient recruitment and enrollment management tool. Not only do EAs utilize my-patient.com to systematically manage patients through the recruitment process, our study-specific prescreening

guides are programmed into my-patient.com to ensure consistent, accurate patient pre-screening. This results in the highest quality patient referrals possible. Moreover, your study team will be provided my-patient.com access allowing your team to view real-time recruitment data, if they so choose.

My-patient.com complies with HIPAA, HITECH, PIHSA, and GDPR data privacy requirements and provides secure, encrypted data storage, access and transmission while allowing for 24/7 transparency into your EAs recruitment efforts.

## PRIVACY

Patient privacy is of foremost concern to WCG ThreeWire. From a regulatory standpoint, there is no barrier to WCG ThreeWire providing Enrollment Assistant support at sites. Privacy requirements pertaining to handling patient data are well understood by WCG ThreeWire. Our Site Services team has been successfully addressing the regulatory requirements at thousands of sites all over the world since 2006.

Our Site Services representative will work with your team to ensure we have the appropriate documentation in place covering our obligations and ongoing compliance with the applicable privacy regulations including: HIPAA, GDPR, PIHSA, and any regionally specific privacy regulations.

## FREQUENTLY ASKED QUESTIONS (FAQS)

### Q. How much will this cost our site?

A. All costs for the WCG ThreeWire Enrollment Assistant are covered by the Sponsor.

### Q. Who will train the EA?

A. No matter what EA placement option you choose, WCG ThreeWire will ensure all EAs have completed training in the following areas:

- Study Protocol
- Good Clinical Practice
- Your site's policies and procedures.
- Applicable patient privacy laws

WCG ThreeWire is also happy to assist with and/or comply with any internal training that may be required by your institution or the study sponsor.

### Q. How long will the EA support last?

A. Support at a site is extremely flexible. The goal is to provide the support you to achieve maximum recruitment results. Your Site Services Team will work with you to develop the scope, timelines, and goals for your site-customized recruitment plan. This could include post enrollment assistance with data entry, query resolution, or patient retention as appropriate.

### Q. How long will it take for support to be implemented?

A. Implementation can be done very quickly. WCG ThreeWire knows that studies often have



competitive enrollment and other timing considerations. Accordingly, when using our standard process, we can typically onboard and EA within 2-3 weeks once we have agreement to proceed.

### Q. Who will manage the EA?

A. Our EA Manager will assume responsibility for the management of the EA supporting your site. This includes training, time and productivity reporting, problem resolutions, and recruitment plan oversight. Day to day, as a part of your study team, the EA is also subject to the investigator's direction.

### Q. How much physical space will the EA need?

A. Approximately the amount of space you would provide for a study monitor. If space is a consideration, let us know and we can work together on a support solution.

### Q. How much time is required of our site staff?

A. The EA will provide time to your team, not require time from your team. Once your EA has an introduction to your site process and systems, they will serve as a full member of your site's study team while executing the established requirement plan. The EA becomes an extra set of hands for your study team to accelerate enrollment.

# Together, We Can Optimize Enrollment Performance

**WCG**

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