LIVE WEBINAR

Key Elements to Outsourcing Clinical Activities in 2024

January 31, 2024 | 9 am ET / 3pm CET

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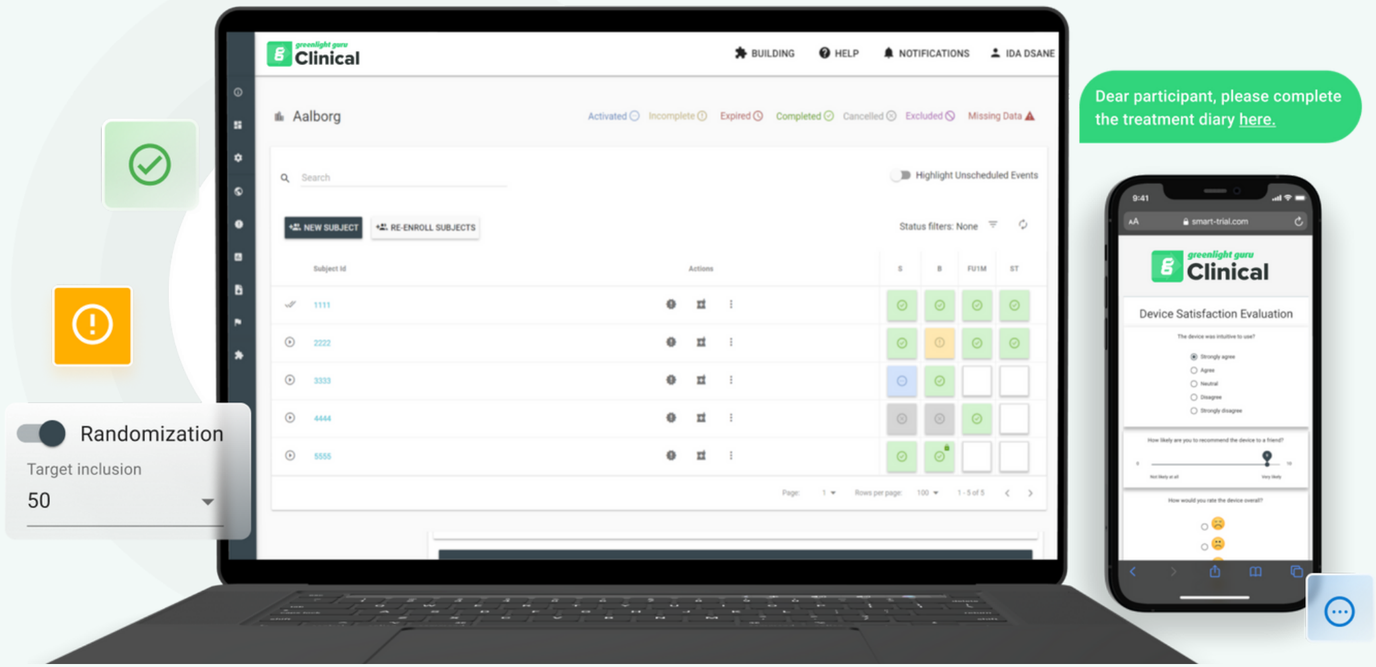

The Leading Toolbox for MedTech Clinical Data Collection

A single, compliant platform for collection and management of all clinical evidence, safety, and performance data.

Learn more here: www.greenlight.guru/clinical

Today's Speakers

Natalie Logeman
Sr. Manager Partnerships,
Greenlight Guru

Chris Rush
Solutions Engineer,
Greenlight Guru

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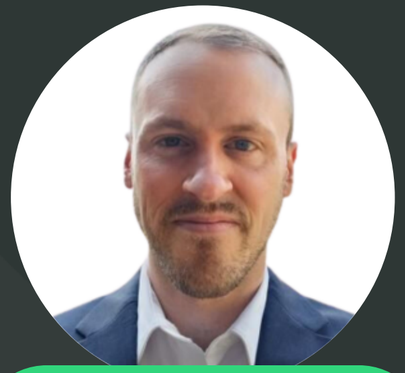
Outsourcing Your Clinical Operations in 2024

Sneak peek into Greenlight's industry survey results, what, when to outsource;



Chris Rush
Solutions Engineer,
Greenlight Guru

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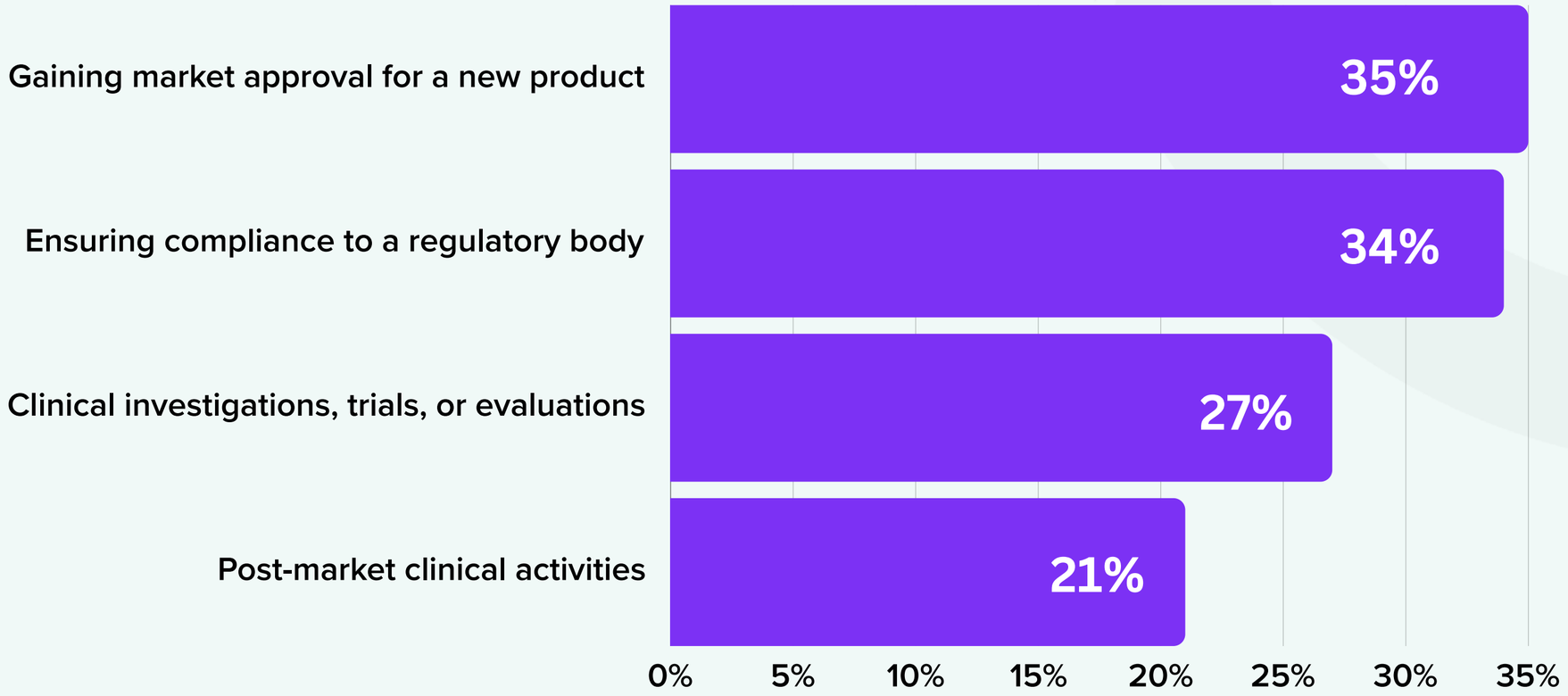
State of the MedTech Industry Benchmark Report

Every year, since 2019, hundreds of MedTech professionals & leaders share their voice on the state of the industry.

The 2024 report features perspectives from 500+ industry voices.

2024 State of the MedTech Industry Report - Top Business Objectives



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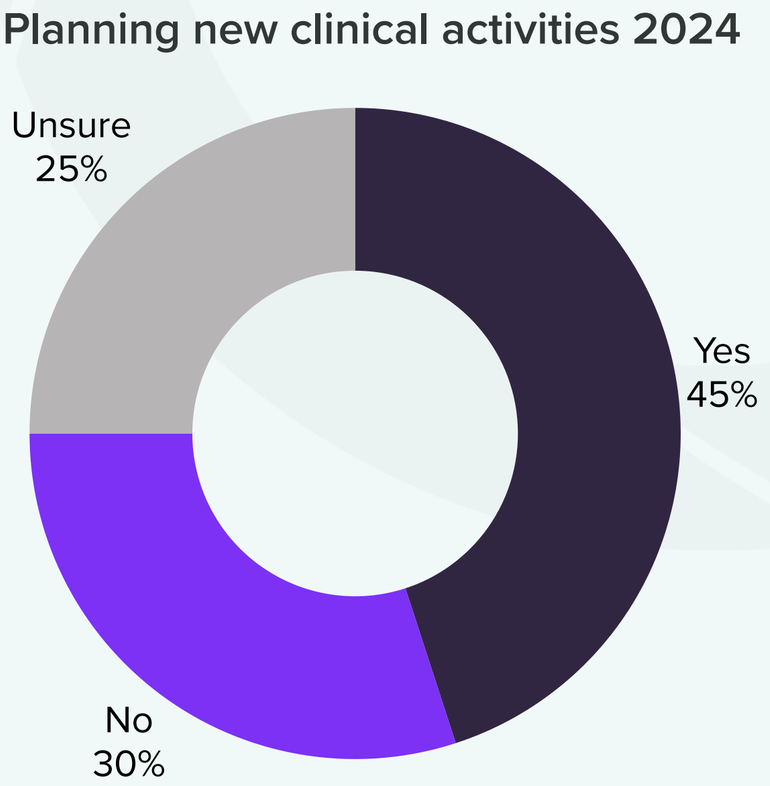
2024 State of the MedTech Industry Report - Themes & Priorities

- “The real push” towards MDR compliance, competing priorities.
- Financial pressure (getting funding is harder)



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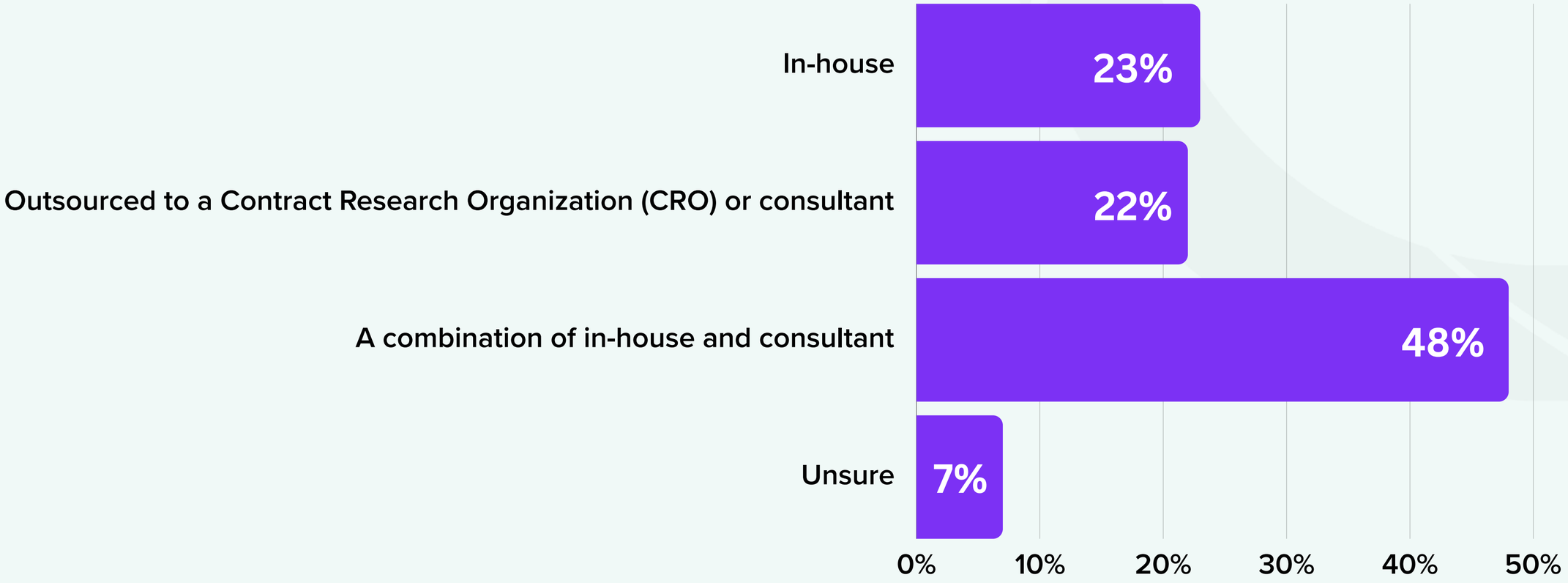
2024 State of the MedTech Industry Report - Conducting Clinical Activities



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Clinical Customer Journey Map

STAGE 1
Innovation

Device Ideation & Prototyping

- Design Concept
- Identify Regulatory Path
- Clinical Study Plan Create

STAGE 2
Strategy

Clinical Strategy, Preparation & Pre-Submission Planning

- Regulatory Planning
- Clinical Investigation Planning
- Data Mgmt Method & Process
- Risk Mgmt Method & Process

STAGE 3
Execution

Clinical Investigation & Study Execution

- Clinical Trial Site Selection
- Clinical Study Build
- Patient Recruitment
- Clinical Electronic Data Collect

STAGE 4
Compliance

Regulatory Submission

- Market Application Submission
- Query Resolution
- Clinical Trial Monitoring
- Device Performance & Efficacy
- Reimbursement Services
- Product Economic Analysis

STAGE 5
Launch

Product Launch

- Clinical Trial Refinement
- Data Assessment
- Insights & Analytics
- Market Assessment

STAGE 6
Assess

Post Market Surveillance

- PMCF, PMS, Peer Reviews, SSCP
- Clinical Study Surveillance
- Data Safety Monitoring
- Post-Market Patient Registries
- Risk Modeling & Future Study Plan
- Market Growth Analysis

STAGE 7
Manage

Regulatory Maintenance

- Supplements
- Amendments
- Annual reports

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Outsourcing Clinical Operations

Traditional aspects

- Writing the clinical protocol
- Contracting (e.g. with sites/investigators)
- Monitoring
- Overall project management

Keep an extra eye on

- Defining primary and secondary endpoints of clinical studies
- Defining key elements in Informed and data processing consent
- Defending the ethics application for your device (why should your study be approved)
- (Patient recruitment & biostatistics)

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How to Select & Work with a Clinical Operations Partner

1. Define your requirements (Consider the SMART approach)
2. Map which requirements can be handled/delivered in-house
3. Test and validate each component.
4. Document results and map back to initial requirements.

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Requirements Cheat Sheet

Key considerations:

- Individual preferences
- Access to specific sites
- Partner’s experience
- Cost and cost structure
- Access to data / digitalization of study
- Patient accessibility / engagement
- Study timelines

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Individual Preferences

Cheat Sheet
(1/7)

We do business with people - not only organizations.

- Recommendation from peers, network or previous relationship
- Punctuality
- Professionalism
- Language capabilities

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Access to Sites

Cheat Sheet
(2/7)

Are there specific sites that would be of strategic importance to your study?

- key opinion leaders (KOLs)
- experience with competitors' products
- clinical workflow that fits your device?
- in a country where you plan to commercialize?

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Partner's Experience

Cheat Sheet
(3/7)

Does the partner have experience within your world and why is that important?

- impact on the partner's ability to provide actionable inputs for study design
- more impact for certain therapeutic areas than others (rare disease)
- should be documented (e.g. via references)

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Cost and Cost Structures

Cheat Sheet
(4/7)

- The cost is “never” what was originally quoted - what does the cost consist of? What are the risks for exceeding costs?
- How is the project cost structured (by patient, by hour, other elements?)
- What would you and your org. prefer? (knowledge of total price over potential savings?)

Access to Data

Cheat Sheet
(5/7)

- Value of data is increasing with developments in AI etc. Access to the raw data is more important than before.
- Can you bring your own EDC system or will you have direct access to the data or system itself?
- Which reports will you get and how frequently?

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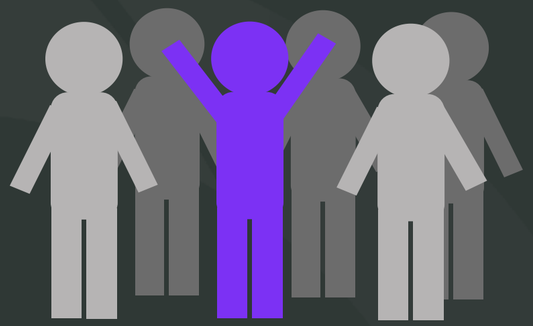
Patient Engagement

Cheat Sheet
(6/7)



- Patient engagement is key for successful recruitment and has a positive impact on data quality.

- If you need Patient Reported Outcomes - does the partner have a documented track record or approach to fulfill your request?

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Study Timelines

Cheat Sheet
(7/7)

Can the partner meet your timelines?

- what is the estimated time to set up your study?
- clinical studies are chronically delayed - what approach will the partner take to mitigate this risk?

What capacity does the partner have to deliver on your study?

- Competing priorities can affect your timelines
- How can you test or document this?

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Outsourcing Your Clinical Operations - So You've Decided to Use a CRO

You're in good company..!

Natalie Logeman
Sr. Manager Partnerships,
Greenlight Guru

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Using a Contract Research Organization (CRO)

- A Contract Research Organization (CRO) is an organization contracted by another company (the sponsor) to take the lead in managing that company's trials and complex medical testing responsibilities.
- Nearly three out of every four clinical trials are conducted by a CRO on behalf of the medical device company

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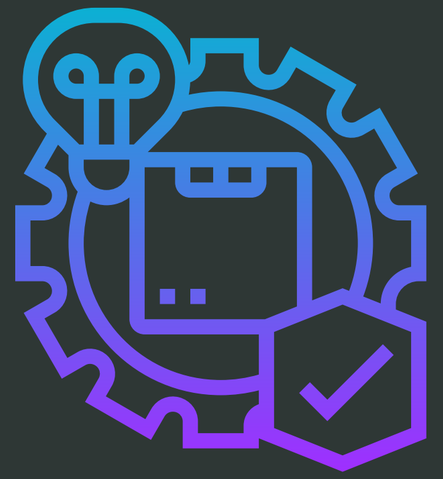
CRO Services

Services provided by a CRO can range widely. A full-service CRO can offer all the services associated with conducting a clinical study, including:

- Pre-clinical services
- Feasibility assessments
- Participant recruitment
- Project management
- Regulatory dossier and ethics submissions
- Phase I, Phase II-III, and Phase IV Clinical Trial Management
- Site Selection
- Trial Monitoring
- Pharmacovigilance
- Statistical Analysis
- Medical Writing



Choosing a CRO - The Process

- Identify the need & create scope of services
- Research CROs and create a short list
- Submit a Request for a Proposal for identified CROs
- Meet with the CRO to refine RFP and discuss project
- Bid defense (if necessary)
- Sign MSA and begin project

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Making the Most of the CRO Decision Process

Good information ♣

- Proposed timeline of the study
- Description of the device + indications

Better information ♦

- ♣
- + Description of the study / synopsis of the proposed protocol
- + Patient information inclusion and exclusion criteria

Best information

- ♣♦
- + All documentation for the proposed study including the protocol
- + Scope of work of what is being done in house vs. outsourced

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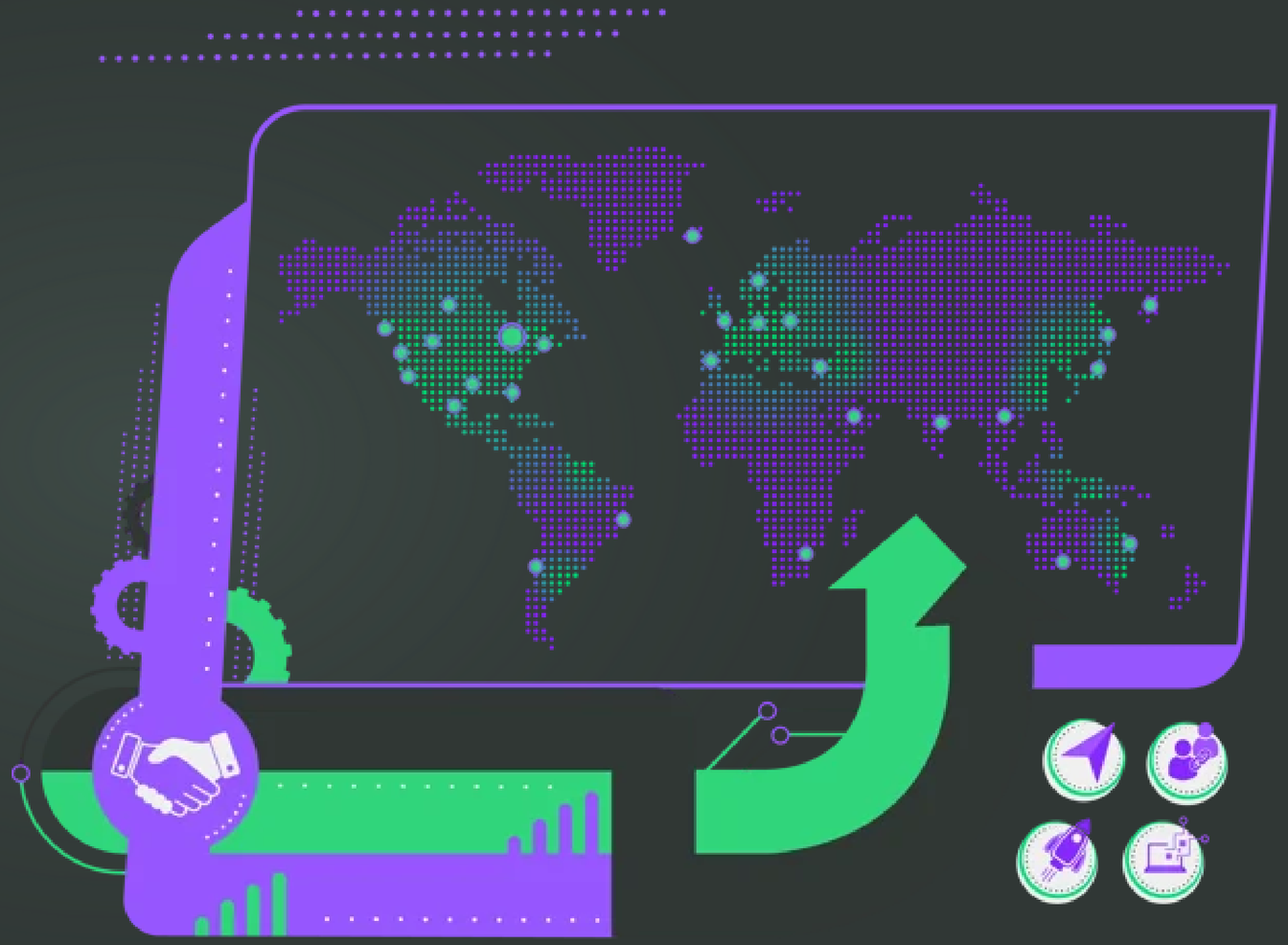
Greenlight Guru Partner Network

Combining expert services of CROs with the leading Electronic Data Capture (EDC) platform purpose-built for MedTech.



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