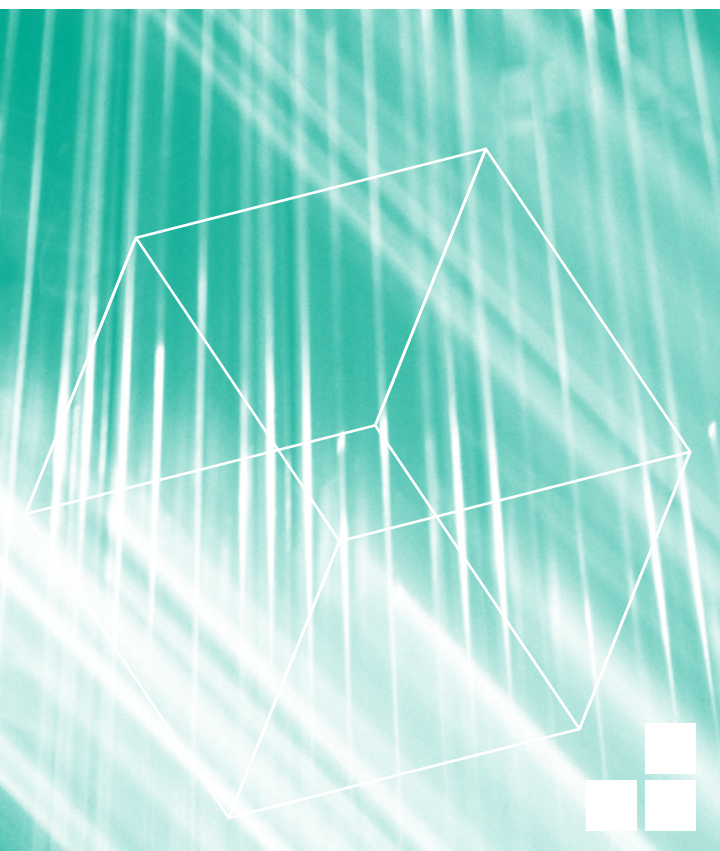




Venture Capital Due Diligence



Arrive at a more accurate valuation

Assessing a medical company for the purposes of venture capital due diligence requires in-depth knowledge of regulatory and clinical strategies, reimbursement, and quality systems in addition to other industry specific processes.

The Regulatory & Clinical Research Institute (RCRI) can deploy a team of qualified experts in these functional areas to assist in your due diligence reviews.

An integrated RCRI team will provide you with a complete analysis that addresses your business objectives.

RCRI knows medical devices, IVDs, biologics, and combination products and the strategy, processes, and timelines involved in moving from concept to market.

Our successful track record spans many medical specialties and includes products ranging from simple modifications of existing products to novel and complex combination products involving drugs, devices, and biologics.

We can help you avoid surprises by asking the right questions early in the due diligence process, so you can prepare more accurate business assessments and valuations.

Due diligence services

Regulatory affairs and clinical trial design & management

RCRI understands the importance of regulatory and clinical strategies in a company's business model.

We offer comprehensive global regulatory and clinical services and will apply that knowledge to venture capital due diligence.

Regulatory

RCRI will analyze and assess:

- Product classification.
- Indication(s) for use.
- Regulatory strategy.
- Establishment registration.
- Device listings.
- QSR, GMP, and GLP compliance.
- Marketing and advertising materials for compliance.
- Competitive product labeling compliance.

Clinical

RCRI will analyze and assess:

- Trial conduct for regulatory compliance.
- The clinical trial design considering regulatory, reimbursement, and marketing requirements.
- Feasibility of clinical trial enrollment.
- Sites, investigators, and/or key opinion leaders.
- Past and current clinical trials both inside and outside the target market.

Due diligence services

Reimbursement planning

RCRI understands the importance of reimbursement to the ultimate financial success of a product. We know what is required to achieve optimal reimbursement. We also have the expertise to analyze available data in terms of generating outcomes and health economics arguments.

RCRI will analyze and assess:

- Existing local and national coverage and determination policies.
- Coding needs.
- Estimated payment levels for a product.
- The payer mix for a product and/or therapy.
- Level of evidence required to support positive coverage determinations.

Quality systems & compliance

RCRI understands global quality and compliance requirements and has significant experience creating quality systems that comply with FDA regulations as well as those of the European Union, Japan, Canada, and Australia.

We will analyze and assess current:

- Quality systems (QSR/GMP/GLP/GTP).
- SOP systems and instructions.
- ISO compliance.
- Licenses and registrations.
- Inspection history and regulatory actions including outstanding actions.
- Regulatory submissions.
- Labeling compliance.
- Postmarket surveillance activities (complaints, MDRs, and annual reporting).
- 21 CFR Part 11 audits.

Flexible services for different applications

Each situation requires a different strategy and a different set of resources. RCRI is committed to developing a package of services to help meet your needs.

We can collaborate with you in individual specialty areas or in several areas depending on the company and proposal involved.

RCRI is flexible. In whatever capacity you choose, you can count on the work of highly qualified RCRI professionals.



Our mission is to serve our clients with knowledge, integrity, and ingenuity

At RCRI, we are proud of our record in providing integrated Contract Research Organization (CRO) services to the medical device, IVD, and biologics industries.

Since our inception in 1999, RCRI has helped nearly 400 companies worldwide translate their product plans into successful revenue generating businesses. Our clients range from development stage start-ups to the largest Fortune 500 companies.

Whether it is a single task or a complex multifaceted project, you can count on the highly qualified professionals at RCRI.

Getting started

Getting started is as easy as making a phone call. During an introductory session, we will discuss and evaluate your needs.

RCRI professionals will start a project with a simple work order. Or, we can develop a formal proposal with detailed timelines, milestones, deliverables, and budgets.

RCRI is committed to helping companies get their products to market approval more quickly, efficiently, and effectively.

Please contact us to discuss how we can assist you.

RCRI is a leader in providing integrated CRO services to the medical device, IVD, biologics, and combination products industries.

RCRI is ISO 9001:2000 certified.



ISO 9001:2000
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