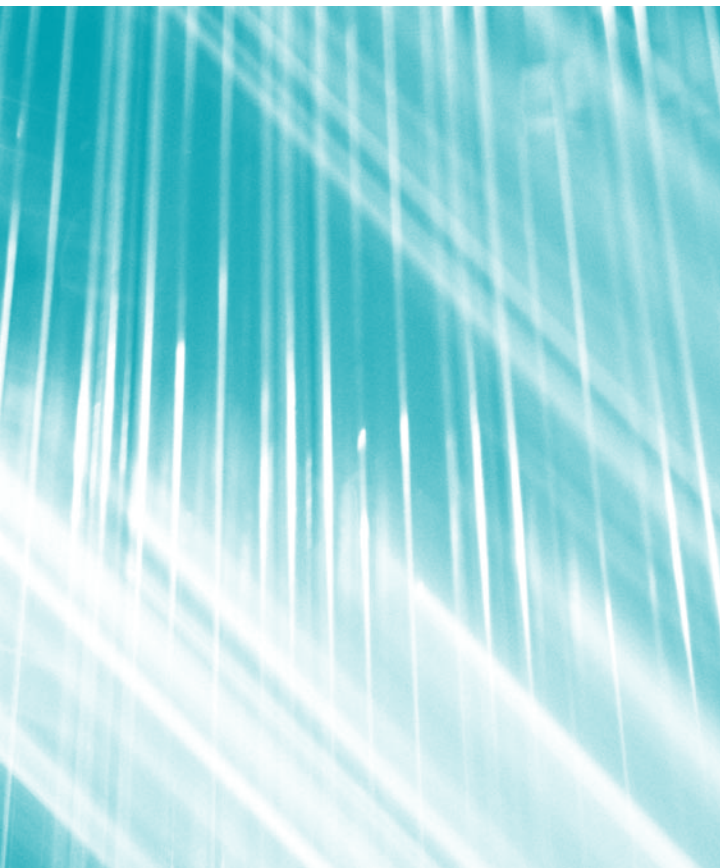




## Reimbursement and Health Economics



## Demonstrate your product's value through early planning

Safety, effectiveness, and outcomes data alone are not enough to earn customer acceptance within today's cost-constrained healthcare environment.

Developing a strong plan to acquire optimal reimbursement is not only a powerful tool for building sales but also for raising venture capital funds.

Building a case for your product through health economic analysis can further support positive coverage and reimbursement decisions for your product.

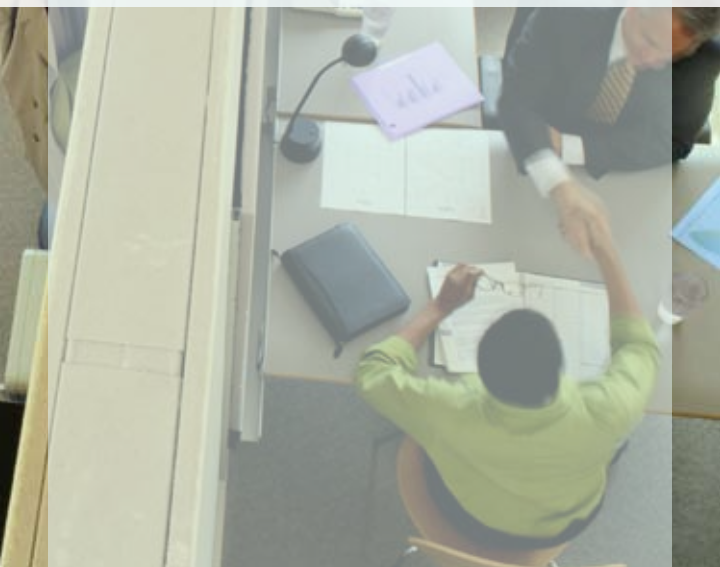
Achieve the best results by starting early. The Regulatory & Clinical Research Institute (RCRI) will integrate reimbursement and health economics into the product development cycle.



## Reimbursement and health economics capabilities

RCRI will:

- Assess the payment environment for your product.
- Identify the activities required to obtain optimal reimbursement from the Centers for Medicare and Medicaid Services (CMS) and other payers.
- Develop a strategic plan with appropriate milestones and timelines for reimbursement activities.
- Train your organization regarding changes in healthcare policies and national trends that could impact your product launch.
- Formulate health economic arguments to support reimbursement activities and sales calls.
- Implement your reimbursement plan by submitting code applications, participating in payer meetings, negotiating for coverage, and preparing supportive documentation and educational materials.



# Working with you to achieve your reimbursement goals

## Assessment

RCRI starts each reimbursement project with a coverage, coding, and payment (CCP) assessment.

The CCP assessment will provide an overview of pertinent:

- Coverage policies.
- Billing codes.
- Code terminology.
- Estimated payment levels.
- Overview of Category A & B reimbursement.

In addition, the assessment will include recommended action items for developing a reimbursement strategy.



## Implementation

After performing a reimbursement assessment, RCRI will work with you to develop and implement a plan to achieve optimal reimbursement levels.

The plan will:

- Assess the viability of reimbursement for your product from a payer perspective.
- Recommend methods of answering reimbursement questions of concern to both regulatory and payer audiences through clinical trial designs.
- Provide estimates of costs for studies and contracts with research centers.
- Develop materials to help hospitals and physicians obtain reimbursement.

The plan will also provide a method of estimating resource requirements; identifying contingency measures; and tracking progress.



## Use health economic analysis to support sales

Health economic analysis supports reimbursement efforts in demonstrating the value of your products.

RCRI uses a variety of analytic tools and economic models to demonstrate:

- Cost-effectiveness.
- Cost-benefit.
- Cost-utility.
- Cost-minimization.

We can perform each of these analyses at single or multiple points in time depending on the product involved and specific client needs.

RCRI also realizes that while economic data collected during a prospective clinical trial provides the most robust conclusions, this data is not always available. Therefore, we can also construct models based on literature reviews.



## Telling the cost-effectiveness story

After your reimbursement plan has been implemented and the health economic analyses have been completed, RCRI can help you tell the cost-effectiveness story to both customers and insurers.

We can support your efforts through:

- Abstracts and posters.
- White papers.
- Journal articles.
- Technology assessments.
- Information packets.
- Sales materials.



## Basic information requirements

To achieve optimal results, it is best to start work on reimbursement and health economic issues early in the product planning cycle.

The coverage, coding, and payment (CCP) assessment – the foundation of a reimbursement plan – is based on three pieces of information that you provide:

- Setting in which the product will be used.
- Patient population.
- Instructions for use.

The CCP assessment addresses the reimbursement environment for both CMS and private payers.



CPT-4  
HCPCS  
RVUs & GPCIs

## Reimbursement and health economics checklist

Use the following checklist to help track your progress on reimbursement and health economics tasks:

- Assess the current coverage, coding, and payment environment for your product.
- Map alternative reimbursement strategies and determine applicable codes and data required to support coverage decisions and sales.
- Identify and integrate economic variables into the clinical trial or post approval study.
- Incorporate the reimbursement strategy into the regulatory and clinical timeline.
- Assess the viability of the chosen strategy through implementation of the clinical and regulatory plan making adjustments for changes in healthcare policy.
- Summarize health outcomes data from the clinical trial.
- Conduct an economic analysis based on the data from the clinical trial and the literature.
- Package the health outcomes and economic analyses in separate formats for insurer and customer audiences.



## **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 bioscience industries.

Since our inception in 1999, RCRI has helped more than 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 multi-faceted 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 9001:2008 certified.



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