

## ABOUT US

[CCREP.ORG.NZ](http://CCREP.ORG.NZ)

CCRep is a research trust specialising in the management of clinical trials. We are based at Middlemore Hospital, South Auckland in New Zealand and have conducted hundreds of clinical trials over 10 years of operation. We provide our trial management services to local and international clients, many of which are market leaders.

Our personnel are highly experienced – our management team shares over 60 years of research management experience in the fields of therapeutics, devices, biotech and other medical intervention studies. The engine room of CCRep is our 20+ highly skilled research nurses and coordinators who work closely with over 30 clinical investigators.

We understand what good research is and what our clients need while maintaining high standards of scientific accuracy and adhering to good clinical practice.

**CCREP CONSULTING**

**CLINICAL DATA AND TRIALS FOR MEDICAL DEVICES AND BIOTECHNOLOGY**

### 1. REFERENCE GROUPS

*Cost:* \$5,000

*Purpose:* To examine clinical viability of product.

*Details:* 4-6 people comprising expert end users (usually physicians), bioengineering, research and finance experts.

2 hours – client-directed discussion based on prepared and circulated information on product and specific areas the client wants to explore.

Can be recorded if required and transcribed within 48 hours.

*Outputs:* Group recommendations and comments will be made as to viability of product. Transcription of reference group discussion (optional).

### 2. DESK RESEARCH

*Cost:* \$5,000 to \$20,000+

*Purpose:* To identify prior research, studies and potential competitors in the area internationally. (Note this is not a replacement of a patent search, which we strongly recommend is carried out by the client).

*Details:* Search of relevant journals, databases, and research sites carried out to discover if comparative products are in development or use. To assess if research exists supporting or discounting the use of similar products or ideas. This is not intended to be a definitive search but to identify indicative information only.

*Outputs:* Written report on findings referencing all examined journals, sites, databases. Written recommendations as to potential competitors and state of research in the market.

### **3. SCOPING**

*Cost:* \$5,000 - \$20,000+

*Purpose:* To develop the scope of a potential trial. This can be done recursively with (4) Protocol Development.

*Details:* Biostatistician, finance and project managers to work up trial requirements. Liaison with hospital departments to assess internal costs, capabilities and feasibility. Cost of trial, statistical review of sample size, identify sites and staffing requirements. This needs to be done recursively with development of a final protocol. A 'quick' budget is initially worked up from client-provided objectives and protocol which is then refined to reach a final estimated budget and resource requirement.

*Outputs:* Study sample size, projected cost, resource requirements including identified PI and potential timelines for trial.

### **4. PROTOCOL DEVELOPMENT**

*Cost:* \$10,000+ (dependent on CCRep input)

*Purpose:* To develop a trial protocol or Clinical Investigation Plan (CIP) and accompanying Statistical Analysis Plan (SAP).

*Details:* CCRep have expert knowledge in trial protocol development. A protocol can only be developed with significant client input. Dependent on the level of client experience CCRep can write a protocol or assist in its refinement. Development of a full protocol is recursive based on the requirements and costs that arise from the scoping exercise.

*Outputs:* Completed trial protocol (or CIP) and SAP

### **5. PERFORM RESEARCH**

*Cost:* \$50,000+

*Purpose:* Complete trial regulatory requirements, staff and perform approved protocol.

*Details:* Following the scoping and protocol process a full research plan is developed and the research carried out. Regulatory requirements such as ethics and internal hospital consulting are attended to. Liaison with external monitor if required, development of Case Report Forms, contract negotiation with external parties, recruit participants and/or administer device/investigational product as necessary under the protocol. Development of database and data entry completed if required.

*Outputs:* Raw research data (within a database of the client's choosing).

### **6. ANALYSE RAW DATA FROM RESEARCH AND REPORT FINDINGS**

*Cost:* \$5,000 - \$100,000+

*Purpose:* To analyse research data and produce a report as to trial outcomes.

*Details:* Statistical analysis of data in accordance with SAP. Report detailing findings on primary and secondary outcomes plus unanticipated or

compound outcomes. Client consultation built into price so may involve a number of iterations.

*Outputs:* Report of research outcomes and full data package (electronic raw data and figures; hardcopy of figures). Report can be in accordance with the FDA Guidance *Structure and Content of Clinical Study Reports* (ICH E3), if required.

## 7. WRITE UP OF RESEARCH RESULTS FOR PUBLICATION

*Cost:* \$10,000 +

*Purpose:* To write up research outcomes in format and style suitable for publication in appropriate journal or other forum.

*Details:* Data package developed consisting of dataset (all analyses), relevant references and documentation, target journal or publication, or report format required. Experienced medical writer consults with client as to publication and writes up results in appropriate style and format. Client consultation built into price so may involve a number of iterations.

*Outputs:* Manuscript ready for submission to journal, or report, or PowerPoint presentation.

## CCREP CONSULTING CLINICAL DATA AND TRIALS FOR MEDICAL DEVICES AND BIOTECHNOLOGY

### GENERAL INDICATION OF TIMELINES DEPENDENT ON CLIENT INVOLVEMENT AND EXPERIENCE

2 MONTHS	Reference Groups Desk Research
2+ MONTHS	Scoping Protocol Development
VARIABLE	Perform Research
3+ MONTHS	Analyse research raw data and report findings.
2 MONTHS	Write up of results for publication

### FOR MORE INFORMATION

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Centre for **Clinical Research**  
and **effective practice**  
*Creating the future of healthcare*

