WHAT IS INVESTIGATOR INITIATED CLINICAL TRIALS?

- CRC wishes to improve Malaysia’s contribution to the therapeutic evidence base, especially in clinical areas relevant to our population’s health.

- Much of these work are undertaken by the pharma & biotech industry usually on a contract basis, and our present contribution in this is sadly negligible, given the dearth of clinical trial publications from Malaysia.

- But it is CRC’s firm conviction that Malaysian investigators are capable of original work too and given the right supporting environment, they could rise to the challenge.
IIT PROGRAM?
CRC appreciates that for quality trials to be conducted in Malaysia and for trial results to be published in reputable international journals, we will need more than just an original idea (which, nevertheless, is still very crucial). We know this because CRC probably has the best track record in clinical trials among Malaysian research institutions.

Investigators will need money, skills and help. As a clinical trial involves patients as human research subjects, investigators will also need to comply with relevant government regulations and international ethical guidelines.

The IIT program was therefore launched specifically to provide practical help to investigators to initiate clinical trials.

The Clinical Research Centre, a partner you can count on, is committed to helping you achieve faster and better results.

Register yourself as a Clinical Investigator with the CRC at www.nmrr.gov.my

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<tr>
<th>#</th>
<th>HOW THE IIT PROGRAM CAN BE OF HELP?</th>
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<tbody>
<tr>
<td>1.</td>
<td><strong>Research Grants</strong></td>
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<td>• CRC allocates research grants for this Investigator Initiated Clinical Trial (IIT) program.</td>
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<td>2.</td>
<td><strong>Compliance</strong></td>
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<td>Practical assistance and subsidies to comply with GCP, NIH research guideline and applicable regulations.</td>
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<td></td>
<td>• Trial registration.</td>
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<td>• Ethics and regulatory authority submission.</td>
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<td>• Trial insurance.</td>
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<td>• Professional indemnity.</td>
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<td>• Contract administration (for Investigator Initiated Clinical Trial (IIT) funded by external third party).</td>
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<td>3.</td>
<td><strong>Trial services</strong></td>
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<td>A range of professional clinical trial services:</td>
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<td>• Trial design and protocol development.</td>
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<td>• Patient Information Sheet/Informed Consent Form development.</td>
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<td>• Study initiation, monitoring and closeout.</td>
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<td>• IVRS central randomization (refer to next page).</td>
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<td></td>
<td>• Data management.</td>
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<td></td>
<td>• Pharmacovigilance.</td>
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<td>• Biostatistics.</td>
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<td>4.</td>
<td><strong>Medical Writing</strong></td>
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<td>CRC provides assistance in writing manuscripts for submission to reputable international journals. CRC probably publishes more clinical trial publications than any other Malaysian research institutions (refer to back page).</td>
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<td>5.</td>
<td><strong>Education &amp; Training</strong></td>
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<td>• Investigators will be given priority to attend CRC’s highly popular GCP certification course, fully sponsored by CRC of course. CRC conducts 12 to 25 of these courses a year around the nationwide.</td>
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<td>• Conduct research training courses particularly for clinical trial:</td>
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<td>- Clinical Trial Design and Protocol Development.</td>
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<td>- Clinical Research Ethics.</td>
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<td>- Clinical Project Management.</td>
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<td>- Clinical Trial Management.</td>
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<td>- Medical Scientific Writing.</td>
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Contact CTU / ACRPM (www.acrpm.com.my) to find out more and to reserve your place.
**What is IVRS Central Randomization?**
A fully integrated system powered by robust IVR (Interactive Voice Response) and Web technologies to support various randomization methods.

**Why you should use this service?**
- High standard and crucial central randomization service in Malaysia.
- Eliminate selection bias and predictability of treatment assignment.
- Reduce phone call cost by using web randomization.
- Security features preventing prank randomization.

**Key Features**
- Around-the-clock, 24/7 availability.
- Randomization via phone or web.
- Simultaneous randomization with multiple phone lines and unlimited Web access.
- Support various randomization methods: simple, block, stratified and etc.
- Supports toll-free 1800 number.
- Data Security: User authentication, encryption, firewall, antivirus and etc.
- Fully automated including randomization reports sending.
- Real-time study recruitment reporting.
- Integrated with other trial systems such as clinical supplies system hence optimizing medication supply chain processes.
- Helpdesk support.

**How does it work?**
It can be easily summed up in the following 3 steps:
1. **ACCOUNT ACTIVATION** (via phone or web).
2. **RANDOMIZATION** (via phone or web).
3. **NOTIFICATION** report sent automatically to you.

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**IVR and Web Randomization Flow Process**

1. **Investigator**
2. **Web Randomization**
3. **Assign Randomization code to Subject**
4. **IVR Randomization**
5. **Randomization database**
6. **Update database**
7. **Generate Randomization Report**
8. **Update database**
9. **Fax and email the Randomization Report**
10. **Sponsors and Monitors**

To access the Central Randomization service, please contact CTU, CRC.
Ongoing IIT projects supported by this program

Already we are witnessing a mini boom in IITs in Malaysia

Ongoing IITs

A. CRC / MOH Funding
- A Phase II, Randomized controlled trial of Foscan®-mediated Photodynamic therapy versus Brachytherapy in patients with Recurrent or Persistent Nasopharyngeal Carcinoma.
- An open labeled, multicentre, randomized phase II trial of combination Gemcitabine and Carboplatin chemotherapy in patients with metastatic or recurrent Nasopharyngeal Carcinoma.
- A multi centre, open label, parallel group, randomized controlled trial to compare the safety and efficacy of oral Paricalcitol versus oral Calcitriol in the treatment of secondary hyperparathyroidism in chronic kidney disease patients undergoing dialysis.
- Impact Of Pharmaceutical Care Programme On Quality Of Life (Qol) in Pediatric Asthma.
- Novel Angioplasty Using Coronary Accessor.
- The Role of Palm Based Vitamin E in Established Diabetic Vasculopathy.
- Randomized Comparison of Coronary Artery Bypass Surgery and. Everolimus-Eluting Stent Implantation in the Treatment of Patients with Multivessel Coronary Artery Disease.


10. A Multicenter, Open label, Randomized Controlled Efficacy study of Direct Coronary stenting comparing to Conventional stenting in Diabetic patients undergoing Elective angioplasty for Coronary Artery Disease (DECIIDE trial). *Am Heart J* 2004; 148: 1007-1101

11. A Randomised, Multi-center, Open label trial to establish the therapeutic equivalence between Carex® and Ultra® in patients on CAPD. *Perit Dial Int.* 2003; 23: (Sup 2) S131-S135

B. International / Other applicable Grants
- Heart Outcomes Prevention Evaluation (HOPE)-3.
- Phase I/II Study of SIR-SHERES® plus SORAFENIB as First Line Treatment in Patients with Non-Resectable Primary Hepatocellular Carcinoma.
- Targeted Oxygenation in Resuscitation of Premature Infants and Developmental Outcome - A Randomised Controlled Trial to evaluate efficacy and safety.
- Identification of Men with a genetic predisposition to Prostate Cancer: Targeted screening in BRCA1 and BRCA2 mutation carriers and controls.
- Comparison of topical Glyceryl Trinitrate ointment and oral Amlodipine in the treatment of chronic anal fissure.
- Study of HEART and Renal Protection (SHARP).
- The ENIGMA-II Trial: Nitrous Oxide anaesthesia and cardiac morbidity after major surgery: a randomised controlled trial.
- Effectiveness in Angle closure Glaucoma of Lens Extraction.